EXHIBIT 1

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE	.)
LITIGATON) MDL No. 1456
) Civil Action 01-CV-12257-PBS
THIS DOCUMENT RELATES TO))
)

DECLARATION OF ELIZABETH A. FEGAN

- I, Elizabeth A. Fegan, pursuant to 28 U.S.C. § 1746, declare as follows:
- 1. I am one of the Plaintiffs' lawyers in the above-captioned case. I personally have been responsible for engaging in discovery in response to defendants' discovery requests on behalf of the United Food and Commercial Workers Union and Employers Midwest Health Benefits Fund ("UFCW"). Throughout this litigation, I have conferred with Lyndon Tretter, an attorney for Bristol-Myers Squibb ("BMS"), with respect to UFCW's production.
- 2. Throughout the course of this litigation, UFCW has produced over 22,000 pages of documents, as well as transactional data covering both brand name and generic prescription drugs for the entire Relevant Period. UFCW also made its Administrator, Daniel Ryan, available for two days of deposition pursuant to Fed. R. Civ. P. 30(b)(6).
- 3. UFCW's consultant on certain pharmacy benefit issues, Segal, also produced approximately 3,500 pages relating to its work for UFCW.
- 4. In response to UFCW's extensive production of claims data related to physicianadministered drugs, on May 13, 2004, Mr. Tretter requested that the Fund also

- produce data related to "other charges," and categorized office visit charges as services "bundled" with the drug price. (See Exhibit A).
- 5. On June 16, 2004, despite the fact that UFCW's data management system appropriately separates the price of drugs purchased from any ancillary charges for office visits, Mr. Tretter again claimed that UFCW "divorced the claims data on the drug itself from the claims data on the administration of the drug." (See Exhibit B).
- 6. On June 23, 2004, my partner Kenneth A. Wexler replied to Mr. Tretter's request for separate claims data in a letter. Mr. Wexler reiterated that UFCW's previous production of its entire "J-Code" claim database was complete. He also wrote that "plaintiffs' claims in this litigation relate only to the price of the drug itself. Therefore, we do not understand why you believe that ancillary charges related to office visits are relevant." (See Exhibit C).
- 7. In addition, on July 8, 2004, I directly addressed the underlying basis of Mr. Tretter's claims. (See Exhibit D). I noted that the plaintiff Funds, including UFCW, produced all transactional data reflecting the drugs at issue during the relevant period, and noted that Mr. Tretter lacked any basis to support the relevance of ancillary charges to the claims or defenses at issue in this litigation. Moreover, I reminded Mr. Tretter that the requested claims data would not establish the providers' costs, and therefore would not assist in proving or disproving his alleged defense. Indeed, I noted that if Mr. Tretter's theory were correct, the relevant evidence used to calculate provider overhead and thereby establish AWP would only be in the possession of defendants. To gain a better

understanding of the claims asserted by BMS, I enclosed a Notice of 30(b)(6)

Deposition addressing the issues raised by Mr. Tretter's requests. (See id.).

8. Mr. Tretter responded to Mr. Wexler's June 23, 2004 letter on July 19, 2004, but

did not directly address any of the issues raised in my July 8, 2004 letter. (See

Exhibit E).

9. Moreover, in Mr. Tretter's July 19, 2004 letter, he notified plaintiffs that he would

seek a protective order against their Rule 30(b)(6) deposition notice, and asserted

that "BMS does not purport to have any such knowledge" related to the delineated

areas of inquiry. (Id.) Mr. Tretter did not explain how any alleged administrative

"shortfalls" could be taken into consideration by defendants when calculating

AWP prices, if they had no knowledge of the prices charged by physicians for

services relative to their costs.

10. On September 15, 2004, in response to defendants' subpoena pursuant to Fed. R.

Civ. P. 30(b)(6), Blue Cross Blue Shield of Illinois ("BCBS") produced two

witnesses to respond to defendants' questions. BCBS' Senior Manager for

Professional Reimbursement Programs testified that there is "no correlation"

between the cost of an office visit and the drug price, and also noted that a change

in the price of an office visit would not affect the cost of a physician-administered

drug. At the time of the filing of this declaration, the transcript for this deposition

was not yet available. As soon as it is delivered, I will provide a copy to the

Court.

Dated: September 15, 2004

Elizabeth Al Fegan

EXHIBIT A



HOGAN & HARTSON

LYNDON M. TRETTER
PARTNER
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May 13, 2004

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WWW.HHLAW.COM

BY OVERNIGHT COURIER

Elizabeth Hartweg The Wexler Firm One North LaSalle Street Suite 2000 Chicago, IL 60602

Re: In Re Pharmaceutical Average Wholesale Price Litigation, MDL 1456

Dear Beth:

We have attempted to analyze the data for physician-administered drugs that UFCW produced prior to Dan Ryan's deposition. However, it appears that UFCW has not provided us with the necessary information to do so. For example, the data includes only the charge for the drug dispensed; we request that UFCW provide all related claims data, since other charges including, but not limited to, the charge for the office visit and any other fees for the drug's administration are relevant to this bundled drug and service. We also request that you confirm that the data set you provided to us encompass all of the physician-administered drug claims for the relevant class period.

In addition, as we have set out in prior correspondence (see my letter dated April 21, 2004), and at Mr. Ryan's continued deposition, there are other documents that UFCW has still not produced despite multiple requests to do so. Accordingly, we request that you immediately produce the following items:

- 1) Amendment No. 2 referenced in the October 23, 2001 Board of Trustee Meeting Minutes (Bates numbered UFCW 16332) and any other amendments, resolutions by the Board of Trustees or meeting minutes related to the "Plan" referred to throughout Segal's "Historical Summary of Benefit and Funding Issues" (Exhibit 30; bates numbered UFCW 0017153 17190).
- 2) A list of Plan participants for whom Medicare is the primary payor.



HOGAN & HARTSON L.L.P.

Elizabeth Hartweg May 7, 2004 Page 2

- 3) Documents evidencing the amounts UFCW charged the "Gary Fund" for prescription drug benefits.
- 4) The February 2nd memorandum referenced in a memorandum dated March 30, 2000 to the Board of Trustees (Exhibit 37; bates numbered UFCW 16604.01).
- 5) Analyses of UFCW's prescription drug outlays (i.e. any data regarding the analysis of increased drug costs as compared to other factors, such as utilization, that may have affected how much the Fund paid for pharmaceutical benefits).
- 6) Data regarding reimbursements UFCW received from a Fund member's primary plan, or other insurance, and any other "records of coordination recoveries" such as Mr. Ryan made reference to in his deposition on April 30, 2004.
- 7) Information or data related to the rebate checks, marked as Exhibit 48 at Mr. Ryan's deposition, including, but not limited to, financial documents and spreadsheets that indicate all the rebates UFCW has received from NPA or Express Scripts.¹
- 8) Unredacted Meeting Minutes where any Segal consultants, or other guests, were present during the discussion of allegedly privileged material. Additionally, we again request a privilege log of all documents that have been withheld on the basis of attorney-client privilege.²
- 9) Exhibits to each of the Board of Trustee Meeting Minutes including, but not limited to, Segal presentations of other exhibits that relate to prescription drug benefits (as you requested at the deposition, we have attached the Meeting Minutes, highlighting the relevant exhibits).
- 10) Documents relating to UFCW's communications with Dominick's regarding its relationship with NPA

¹ We also ask that you confirm that UFCW has produced a complete set of all the rebates received by any prescription benefit manager to date.

² Also, please produce the resolution authorizing UFCW to bring this or any predecessor lawsuit.



HOGAN & HARTSON L.L.P.

Elizabeth Hartweg May 7, 2004 Page 3

11) Documents responsive to our discovery demands in the possession of any UFCW trustee including, but not limited to, any Segal presentations or exhibits referenced to in Board of Trustee Meeting Minutes.

Lastly, it is apparent from the discovery taken to date that UFCW has not searched and produced responsive documents from various sources within its possession, custody and control. Therefore, we once again ask that you confirm that UFCW has searched and produced electronic documents from the hard drives, e-mail, correspondence and work files of every person who may possess information regarding UFCW's reimbursement for prescription drugs, health benefits provided by UFCW or pharmacy contract negotiations.

Very truly yours,

Lyndon M. Tretter

LMT/spk

Enclosures

cc: All counsel of record via Verilaw

EXHIBIT B



HOGAN & HARTSON

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June 16, 2004

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WWW.HHLAW.COM

BY FAX AND VERILAW

Elizabeth Fegan, Esq. The Wexler Firm One North LaSalle Street Suite 2000 Chicago, IL 60602

> Re: In Re Pharmaceutical Average Wholesale Price Litigation, MDL 1456

Dear Beth:

This is to reply to your letter of June 4, 2004, which you write was intended to respond to my letter of May 13, 2004 regarding UFCW's document production. Unfortunately, you have ignored several aspects of my letter. We need to resolve these issues right away.

First, I previously wrote that, with respect to data on physician-administered drugs, UFCW seems to have divorced the claims data on the drug itself from the claims data on the administration of the drug. I wrote that we need the entire set of claims data, "since other charges including, but not limited to, the charge for the office visit and any other fees for the drug's administration are relevant to this bundled drug and service." Also, since the limited data you provided only went back to 1994, I wrote that "[w]e also request that you confirm that the data set you provided to us encompass all of the physician-administered drug claims for the relevant class period." You have not said anything on either of the above points. Please either provide the data or let me know why you decline to do so.

Second, I requested that UFCW search for documents stored in electronic form responsive to defendants requests, like e-mails and word-processed documents. Again, your letter is silent. Considering the pains to which plaintiffs



HOGAN & HARTSON L.L.P. Elizabeth Fegan, Esq. June 16, 2004 Page 2

have put defendants in terms of producing electronic discovery, I do not see how plaintiffs can justify not making electronic searches of themselves.

Third, while you do deal directly with my request that you search the files of the UFCW trustees for responsive documents (by objecting to it as "overly burdensome and harassing"), I am asking you to reconsider. I have read your June 11, 2004 letter to Kim Harris in which you analogize the plaintiff funds' trustees to the members of the boards of directors of the defendants. That analogy simply does not hold up. The plaintiff funds in this case are very small organizations. They generally have no operational management above an administrator and the administrator has no decision-making power on the matters at issue in this litigation. Conversely, corporate boards of directors rely on fairly large organizations comprising numerous levels of officers and employees who are responsible for the operation of the business and therefore board members do not receive or work with the kind of documents or data likely to be relevant in this litigation.

Moreover, I have asked you to search the UFCW trustees' files specifically because documents that I would expect the administrator, Dan Ryan, to have (such as Segal reports to the trustees) were not previously produced. Indeed, if we had not subpoenaed Segal, we might not have received some of the most important documents in the case with respect to UFCW. I suspect that these documents (and probably more) are in the possession of the trustees and that therefore UFCW has not engaged in good faith discovery. One final thought on this point: if on the other hand, no one on behalf of UFCW, including the trustees, has the missing documents, then it appears that UFCW has engaged in spoliation of relevant evidence.

Fourth, you have not responded to paragraph #6 in my May 13 letter seeking, "Data regarding reimbursements UFCW received from a Fund member's primary plan, or other insurance, and any other 'records of coordination recoveries' such as Mr. Ryan made reference to in his deposition on April 30, 2004." Such data is absolutely necessary to make sure that UFCW is not seeking money for drugs for which it was reimbursed from another source.

Fifth, you have not responded to my request (and to the Court's order) that you produce a log of documents withheld on the ground of privilege. I am not referring here simply to meeting minutes you that have redacted (we believe, improperly), but to other kinds documents that have been completely withheld.



HOGAN & HARTSON L.L.R Elizabeth Fegan, Esq. June 16, 2004 Page 3

Finally, you write that you are not aware of the existence of a written "resolution" by the UFCW trustees authorizing this or a related earlier lawsuit. However, if there is <u>any</u> evidence of the trustees' having authorized this suit, such as a reference in a meeting minute or a communication to Mr. Ryan, we believe that is fairly encompassed in our request. Alternatively, if you are saying that the authorization was "oral" please inform us of when and how this was communicated.

I would appreciate your giving me a response by the end of next week. We are at the point where we must seek the Court's assistance if we cannot resolve these matters promptly.

Very truly yours,

Lyndon M. Tretter

cc: All counsel of record via Verilaw

EXHIBIT C



THE WEXLER FIRMLLP

June 23, 2004

Mr. Lyndon Tretter Hogan & Hartson, L.L.P. 875 Third Avenue New York, NY 10022

In re: Pharmaceutical Industry Average Wholesale Price Litigation

MDL No. 1456

Dear Mr. Tretter:

Re:

This is in response to your letter of June 16, 2004, regarding UFCW's production of documents.

First, you assert that UFCW's claims database for physician-administered drugs is insufficient without including claims data on the administration of the drug. We disagree. UFCW has produced the entire "J-Code" database it has reflecting reimbursements for drug purchases that were administered by a physician. Plaintiffs' claims in this litigation relate only to the price of the drug itself. Therefore, we do not understand why you believe that ancillary charges related to office visits are relevant. Please advise.

Second, you request the production of additional documents in electronic form, including e-mails and word processed documents. UFCW is conducting a search for these documents. We expect to produce to you whatever responsive documents there are by July 2, 2004.

Third, you again request responsive documents from the files of the current and former UFCW trustees. All of the Plaintiff Funds have objected to this request as overbroad, duplicative, overly burdensome, harassing and unlikely to lead to the discovery of admissible evidence. In your letter, you maintain that simply because Plaintiff Funds are smaller organizations than the defendants, their trustees should be subject to burdensome document searches from which the defendants' board members are exempt. There is no basis for this assertion. We stand by our objections.



THE WEXLER FIRM LLP

Mr. Lyndon Tretter June 23, 2004 Page 2 of 2

As Beth Fegan stated in her letter to Kim Harris on June 16, 2004, UFCW has already produced the minutes of its trustee meetings, as well as relevant hand-outs and exhibits. As you admit, defendants have subpoenaed UFCW documents from Segal. Your insinuations that documents may be "missing," or that there has been spoliation, are groundless. If you believe that a particular trustee or trustees have specific documents that you do not have, please advise and we will discuss it. Otherwise, from our perspective, the matter is closed.

Fourth, you request "data regarding reimbursements UFCW received from a Fund member's primary plan, or other insurance, and any other 'records of coordination recoveries' such as Mr. Ryan made reference to in his deposition on April 30, 2004." Reimbursement by coordination recoveries is a factor in approximately 1% of UFCW's pharmaceutical payments. The data for these recoveries is not maintained in a readily accessible form. The searching for and compiling of this data would be a highly burdensome task that would yield little helpful or relevant information for your purposes. Under these circumstances, we ask you to reconsider this request.

Fifth, you ask for the production of a privilege log. We have provided one, but will provide a supplemental log by July 2, 2004.

Finally, you again request evidence of a resolution "authorizing this or a related earlier lawsuit." As you note, we have previously told you that we are not aware of the existence of a written resolution. Moreover, as discussed above, we have produced all of the meeting minutes and related documents for the relevant time period. We are investigating your comments about an "oral" authorization and will advise you accordingly.

If you have any further questions, please let me or Beth know.

Very truly yours,

Kenneth A. Wexler

KA Wayber/ASS

KAW/jb

cc: Elizabeth A. Fegan

All counsel via Verilaw

EXHIBIT D

THE WEXLER FIRM LLP

July 8, 2004

Via Verilaw

Mr. Lyndon Tretter Hogan & Hartson, L.L.P. 875 Third Avenue New York, NY 10022

RE: In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456

Dear Lyndon:

As you know, plaintiff Funds have produced or made every effort to produce all transactional data reflecting the payments that they have made for all branded and generic drugs (and not just the AWPIDs) in their possession or control for the Relevant Period, in accordance with the global agreement reached with Kim Harris in November 2003.

Now, you are requesting the production of fund payments for office visits and administration related to Medicare Part B-covered drugs that are administered and paid for outside of Medicare Part B. You stated that this information is related to the manufacturers' defense that the AWP spread was used to help make up for the alleged shortfall that the providers suffered in the cost of administration.

First, there is no evidence that the defendants' fraudulent inflation of AWPs was: (i) only related to AWPs for Medicare Part B-covered drugs; or (ii) at all done in order to make up for administration shortfalls. Second, an individual fund's payments for a bundle of services will not demonstrate what the providers' costs were or whether insurance payments overall were sufficient to cover them. Third, in the event that the manufacturers' defense is true, the manufacturers will possess the relevant information, i.e. the data used to calculate provider overhead and administration costs before the manufacturers established the AWP and spread on a drug. Accordingly, there is no reason to burden and harass the funds, or their third party administrators or insurers, for information that is not reasonably calculated to lead to the discovery of admissible evidence.

THE | WEXLER | FIRM LLP

Mr. Lyndon Tretter July 8, 2004 Page 2 of 2

However, in the interests of good faith, we are willing to explore these issues further with BMS and reconsider our position if we are wrong. Accordingly, enclosed herewith please find a Notice of 30(b)(6) deposition for BMS related to this issue.

Sincerely,

Elizabeth Al Fegan

EFH:lyr

Enclosure

cc: All Counsel of Record via Verilaw (w/o encl.)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339

NOTICE OF RULE 30(B)(6) DEPOSITION OF BRISTOL MYERS SQUIBB

TO: All Counsel of Record via Verilaw

PLEASE TAKE NOTICE that the undersigned attorneys for Plaintiffs shall take the deposition upon oral examination of the person most knowledgeable at **Bristol Myers Squibb** in this action regarding the matters designated on Exhibit "A," attached. This deposition will be taken pursuant to Federal Rule of Civil Procedure 30(b)(6) and will be recorded by stenographic and/or sound and visual means. The deposition will be take place as at 9:30 a.m. on July 22, 2004 at Hagens Berman LLP, One Main Street 4th Floor, Cambridge, MA 02142.

You are invited to attend and participate.

Dated: July 8, 2004

Jeffrey Kodroff John Macoretta Spector, Roseman & Kodroff, P.C. 1818 Market Street, Suite 2500 Philadelphia, PA 19103

Tom Sobol Edward Notargiacomo Hagens Berman LLP 225 Franklin Street, 26th Floor Boston, MA 02110

Steve W. Berman Sean R. Matt Hagens Berman LLP 1301 Fifth Avenue, Suite 2900 Seattle, WA 98101

Samuel Heins Brian Williams Heins, Mills & Olson, P.C. 3550 IDS Center 80 South Eighth Street Minneapolis, MN 55402

CHAIRS OF LEAD COUNSEL COMMITTEE

Marc H. Edelson Hoffman & Edelson 45 West Court Street Doylestown, PA 18901

Kenneth A. Wexler Elizabeth A. Fegan The Wexler Firm LLP One North LaSalle Street, Suite 2000 Chicago, IL 60602

MEMBERS OF LEAD COUNSEL COMMITTEE AND EXECUTIVE COMMITTEE

EXHIBIT "A"

INSTRUCTIONS

All of the definitions from Plaintiffs' First Requests For Production of Documents Directed to All Defendants are incorporated herein by reference.

"AWPID" refers to all of the drugs identified in Exhibit A of the proposed Amended Master Consolidated Class Action Complaint.

"Spread" refers to the difference between AWP or any price upon which reimbursement for a drug is based, on the one hand, and the actual or net price paid for a drug on the other hand.

Unless otherwise specifically stated, each of these Areas of Inquiry encompasses the years 1991 through the present.

AREAS OF INQUIRY

- 1. The alleged shortfall that doctors or providers purportedly suffered in the cost of administration of any AWPID.
- 2. The identity of the employees involved in the process of establishing, stating, changing or setting the AWP and/or spread in order to help make up for the alleged shortfall that the providers purportedly suffered in the cost of administration of any AWPID
- 3. The identity of all documents related to any contention that the AWP and/or spread was used to help make up for the alleged shortfall that the providers purportedly suffered in the cost of administration of any AWPID.
- 4. The identity of all documents related to any attempt to determine, calculate, evaluate or quantify a provider's cost to administer any AWPID.

- 5. The identity of all documents related to any communications with any doctor or provider regarding the alleged shortfall purportedly suffered in the cost of administration of any AWPID.
- 6. The process by which Bristol Myers Squibb analyzes, calculates, determines or otherwise considers the alleged shortfall that the providers suffered in the cost of administration of any AWPID.
- 7. The process by which any pharmaceutical manufacturer analyzes, calculates, determines or otherwise considers the alleged shortfall that the providers suffered in the cost of administration of any AWPID.





Pharmaceutical Industry Average Wholesale Price Litigation

Confirmation

Logged in User: Yolanda Rivera

Your request has been successfully received! The cost of this submission is \$12.00. Faxed and overnight documents will incur an additional charge of \$0.30 per page. The account will be charged after the processing of the document is complete.

Confirmation number: AWP2262767

Date: Jul 8, 2004 Time: 2:01:02 PM EDT

Click here to print this page for your records.

Review Order Authorizing eService Billing Code: 1075-012

Case: AWP All Cases: AWP-MDL No.1456

Description: Letter from Ms. Elizabeth A. Fegan to Mr. Lyndon Tretter; Notice of Rule

30(b)(6) Deposition of Bristol Myers Squibb

Help Desk: (610) 205-1040, ext. 1

Email Help Desk

A cel Acrobat' Reader Submit another document in this case

EXHIBIT E



HOGAN & HARTSON

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July 19, 2004

BY FAX AND VERILAW

Kenneth A. Wexler, Esq. The Wexler Firm One North LaSalle Street Suite 2000 Chicago, IL 60602

> Re: In Re Pharmaceutical Average Wholesale Price Litigation, MDL 1456

Dear Mr. Wexler:

This is to reply to your letter of June 23, 2004 regarding UFCW's document production and to fulfill defendants' "meet and confer" obligation prior to making a motion to compel discovery.

On physician-administered drugs, our position is clear: one cannot look at the reimbursement of the drug in the abstract. Physicians and reimbursers negotiate prices based on both the drug and the services related to administering the drug. Indeed, in the Medicare Part B program, Congress and CMS (formerly HCFA), have for years noted that AWP-based drug reimbursements "cross-subsidize" low fees for drug administrative services and the practice component of reimbursement. Similarly, pharmacy-dispensed drugs often involve both an ingredient cost (drug) and a dispensing fee (service). UFCW has shown no resistance to disclosing the dispensing fees. Why UFCW insists on producing only the drug information and not the related claims information for physician-administered drugs is a mystery.

We intend to bring this issue to the attention of the Magistrate Judge unless you agree to produce full information (with the exception of patient identifying data) for those claims that involve physician-administered drugs and for which UFCW seeks recovery in this lawsuit. At the same time, we will move for a



HOGAN & HARTSON LLP Kenneth Wexler, Esq. July 19, 2004 Page 2

protective order against the deposition notice plaintiffs recently served upon Bristol-Myers Squibb Company ("BMS") for a witness with knowledge of the link between reimbursement for physician-administered drugs and for reimbursement for the related services. As I have told Beth Fegan of your office, BMS does not purport to have any such knowledge. Rather, this is a fact about public and private reimbursers that I and other counsel have learned during the case. Indeed, it is clear that the deposition notice addressed to BMS was served simply as a "kneejerk" reaction to my continuing to seek this discovery from UFCW.

On the search of the UFCW trustees' files, we have limited our request to a search of documents relating to communications with The Segal Company. We have asked that the trustees' files be searched for these particular documents because we know that they exist and the Administrator's office has not been able to provide them to us. Please let me know if you are refusing even this limited request.

I am willing to reconsider our request for "Data regarding reimbursements UFCW received from a Fund member's primary plan, or other insurance, and any other 'records of coordination recoveries" if UFCW will stipulate that it is unable for the purposes of this litigation to specify the drugs for which it was reimbursed from another source. Otherwise, we must have the information.

On privilege issues relating to Board of Trustee meetings minutes, we have established that UFCW improperly redacted those portions of trustee meeting minutes where Segal and other visitors were present when the alleged legal advice was given. Please produce the full minutes immediately.

In addition to the above, I look forward to receiving (a) the electronically-stored documents you refer to in your letter (which you said that you would supply by July 2nd) and (b) the results of your investigation into whether and in what form the UFCW trustees authorized this lawsuit.

Very truly yours

L√ndon M. Trettei

cc: All counsel of record via Verilaw

EXHIBIT 2

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE)
LITIGATON) MDL No. 1456
) Civil Action 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)
) Judge Patti B. Saris
)

DECLARATION OF ANTHONY J. SIEVERT

I, Anthony J. Sievert, pursuant to 28 U.S.C. § 1746, declare as follows:

- I am one of the Plaintiffs' lawyers in the above-captioned case, and am one of the
 attorneys responsible for working with United Food and Commercial Workers
 Union and Employers Midwest Health Benefits Fund ("UFCW") to respond to
 defendants' discovery requests.
- 2. Following UFCW's production of transactional claims data, on March 22, 2004, I arranged a telephone conference with Sandhya Kawatra, the attorney for BMS, and Ed Mohr, UFCW's database manager. Through this informal dialogue, UFCW permitted BMS to resolve any technical computer issues related to the database.
- 3. On June 22, 2002, UFCW's computer personnel were instructed to conduct a search for all potentially relevant electronic mail that had been produced during the Class Period. I confirmed that the UFCW employees who have access to e-mail include only department heads, nurses and computer programmers. Of the

UFCW personnel with access to e-mail, the only two with potentially relevant information are Daniel Ryan and Janet Adachi.

- On July 2, 2004, I received the complete record of e-mails that exist on Mr.
 Ryan's computer. On July 19, 2004, I received the complete record of e-mails on Ms. Adachi's computer system.
- 5. On July 28, 2004, I personally visited UFCW's offices and reviewed each and every e-mail that resided on both Mr. Ryan's and Ms. Adachi's computers. UFCW does not maintain any servers or backups that could have contained additional documents to be produced by either Mr. Ryan or Ms. Adachi. UFCW's e-mail system maintains documents only on the user's hard drive, rather than duplicating them on a separate server for later recovery. Moreover, a user of UFCW's computer system cannot access his or her prior received or sent e-mail on any other computer.
- On August 20, 2004, UFCW produced 132 pages of e-mail documents responsive to defendants' requests.
- 7. On August 24, 2004, I spoke with Sandhya Kawatra, counsel for Bristol-Myers Squibb, and discussed UFCW's e-mail production. I informed her that the documents that UFCW produced constituted the universe of responsive e-mails residing on Mr. Ryan and Ms. Adachi's hard drives. I explained that Ryan and Adachi are the only two individuals with access to e-mail who are likely to possess any relevant documents.

FURTHER AFFIANT SAYETH NOT.

Dated: September 15, 2004

EXHIBIT 3

Volume II

Chicago, IL

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289
 1
              IN THE UNITED STATES DISTRICT COURT
 2
               FOR THE DISTRICT OF MASSACHUSETTS
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     IN RE PHARMACEUTICAL
 5
     INDUSTRY AVERAGE WHOLESALE ) MDL No. 1456
 6
     PRICE LITIGATION
                                 ) Civil Action: 01-CV-12257-PBS
 7
     THIS DOCUMENT RELATES TO
                                 )
     ALL CLASS ACTIONS
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10
                  Continued Deposition of DANIEL RYAN, taken
     before GREG S. WEILAND, CSR, RMR, CRR, Notary Public,
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     pursuant to the Federal Rules of Civil Procedure for
     the United States District Court pertaining to the
13
     taking of depositions, at Suite 900, 11 South
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15
     LaSalle Street, in the City of Chicago, Cook County,
     Illinois, commencing at 9:35 o'clock a.m., on the
16
17
     30th day of April, 2004.
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Daniel Ryan Volume II

Chicago, IL

April 30, 2004

304

5 (Pages 302 to 305)

302 1 (Witness sworn.) BY MR. TRETTER: 1 2 DANIEL RYAN 2 Q. Exhibit UFCW 028 looks like some e-mails between 3 after being first duly sworn, testified as follows: Janet Adachi, who I guess works for you, and 3 4 CONTINUED EXAMINATION 4 somebody at ExpressScripts. 5 BY MR. TRETTER: 5 Sometimes if you read it from the bottom 6 Q. Good morning, Mr. Ryan. I'm still Lyndon up it's helpful. It looks like the first entry was 7 Tretter, and we're here for the continuation of your Janet Adachi was writing to somebody at ExpressScripts about the Funds going to a mandatory 8 deposition in this matter. I guess when we last 9 spoke, I'm looking at the transcript, it was the 9 generic, and she asked what would be involved to 10 16th of March, 2004. 10 make this transition. 11 Have you had an opportunity to look at 11 12 your transcript? 13 A. I did look at it. 13 14 Q. Okay. Is there anything that you want to 14 mandatory generic? 15 change? 15 A. I do. 16 A. No. 16 Q. What's that? 17 17 Q. Have you done anything else with respect 18 to this litigation in terms of search for documents 18 19 or review materials between the time of your first 19 20 day of testimony and today? 21 A. Yes. 21 22 Q. What have you done?

First of all, do you have some understanding of what it means when you're asking -this is in I guess June 12, 2002 - about going to A. One of the cost containment provisions that we considered for some time was to impose a mandatory generic requirement where a participant if a generic drug was available, they would have to take that, they would have to use that drug. If they didn't, we would limit our payment to what we would have paid for the generic drug. Q. Was that change ever made? A. It was made.

303 1 A. We had the counsel from Wexler's office 2 assist my secretary in going through our files and 3 obtaining documents. 4 We also got a letter from you through 5 counsel asking for specific documents, and we assisted them in developing some of them. 6 Q. Okay. Is there anything else that you 7 8 have done personally besides giving letters to assistants or directing them to look for particular 9 10 types of documents? 11 A. I looked through my departmental file on 12 drugs and didn't find anything related to pricing. 13 Q. Okay. Any more deposition preparation 14 that you did? 15 A. I did not. I want to show you one of the 16 documents that I believe we recently got. It looks like an e-mail trail, and I think we're up to 17 18 Exhibit, what, 28. We did 27A and B, so I think 19 we're up to Exhibit UFCW 028. 20 We will make this Exhibit UFCW 028. 21 (Exhibit UFCW 028 marked as

- requested.)

22

305 Q. What was that? A. That was made on January 1st, 2004. Q. So that's effective with the new PBM that you're using? A. It is. Q. And who is that PBM? A. NMHC. Q. This is one of the few e-mail documents that we received in your Fund's document production. I take it most people that work for the Fund do have access to e-mail or have had access to e-mail for several years? A. It's a primarily management only, and I think it's been maybe two or three years. Q. When you say management, who would be those people? A. The department heads and their assistants, our nurses and the computer programmers. Q. Was any search made in response to our

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Daniel Ryan Volume II

Chicago, IL

April 30, 2004

6 (Pages 306 to 309)

-			
	l beginning document demands or more recent ones of	6	308
1	2 e-mail systems at the Fund?		which we will mark as 29. This is another document
1	3 A. We tend to delete. We tend to delete our	3	- Jan Bar and of the recent decalifely
	4 e-mails. But I did, I went into my search engine,	4	production. For the record, it has I'm sorry,
1	the Outlook system, and put in drugs, these types of		let me get the reporter to mark it.
1	6 keywords and whatnot, and didn't come up with	5	(Exhibit UFCW 029 marked as
1	7 anything meaningful.	6	requested.)
1	8 Q. Was that done for anybody else besides	7	BY MR. TRETTER:
1	9 yourself?	8	Q. The reporter has marked Exhibit UFCW 029 now.
	-	-	Why don't you take a moment to look at it. It looks
1		10	like several documents that were stapled together.
			I'm going to primarily be interested, I think, in
1	•	12	the first page.
1		14	For the record, it's UFCW 17085 through
1:	5 your assistant or secretary keep documents on hard	15	93. The first page is a memorandum from Mr. Ryan to
10		16	three people. It's dated July 15th, 1997, and it's on Medicare issues.
l r		17	A. Okay.
11		18	•
19		19	Q. Do you recall on the first day of your
20		20	deposition we talked about the certain circumstances
2	Q. Okay. Was a search made of other people's	21	where the Fund might pay secondary to Medicare? Do you recall that?
22		22	A. Yes.
			7. 105.
	307		200
1	A. Mine and my secretary's I believe, but	1	Q. And this memorandum deals with that issue;
2	! nobody else's.	2	is that correct?
3	The world ask that other	3	A. It does.
4	i / market and in presemption drugs of	4	Q. You write under the paragraph that begins
5	that arrives be	5	Segal memo, in summary, the Segal, and Segal is
6	and the same and t	6	S-e-g-a-l, memo advises that a health plan must
7	The state of the categories again of	7	request an exception to the, quote, Medicare as
8	• •	8	secondary, closed quote, rule when a participant
9	The Treat Tele. Well, anybody that Hight	9	works for an employer that has fewer than
10	I The state of the	10	20 workers, period. We are not presently doing
11	July man and a man access	11	that, period.
12	B Fi Bird ob a broader	12	What had you been doing up until the time
13	z i i i i i i i i i i i i i i i i i i i	13	of this memo?
14	. B. F. and the state that	14	A. When a claim came in where the person
15	3	15	worked for an employer less than 20 and had
16	,	16	Medicare, we paid secondary to Medicare.
17	, and a second titlett	17	Q. But you hadn't formally requested an
18	in the state of th	18	exception?
19	To be think by	19	A. We had not.
20	Just put it uway.	20	Q. So what did you do after the time of this
21	Right there is fine.	21	memo?
22	Why don't we go to the next document,	22	A. Going down to the next paragraph where we
	•		

EXHIBIT 4

United States General Accounting Office

GAO

Report to Congressional Committees

October 2001

MEDICARE PHYSICIAN FEE SCHEDULE

Practice Expense
Payments to
Oncologists Indicate
Need For Overall
Refinements

Headings for Appendix II and III corrected on 05/03/04. Printed copies of this report were correct.



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Abbreviations

AMA	American Medical Association
ASCO	American Society of Clinical Oncology
CPEP	clinical practice expert panel
CMS	Centers for Medicare and Medicaid Services
E&M	evaluation and management
HCFA	Health Care Financing Administration
PEAC	Practice Expense Advisory Committee
RUC	Relative Value Update Committee
RVU	relative value unit
SCHIP	State Children's Health Insurance Program
SMS	Socioeconomic Monitoring System



United States General Accounting Office Washington, DC 20548

October 31, 2001

Congressional Committees

Medicare's physician fee schedule establishes payments for more than 7,000 different services, such as office visits, surgical procedures, and treatments. Prior to 1992, fees were based on charges physicians billed for these services. Since then, in accord with a statutory requirement, the Health Care Financing Administration (HCFA), which administers the Medicare program, has been phasing in a new fee schedule that bases the payment for each service on the amount of resources used to provide that service relative to all other services. The first part of the resource-based fee schedule, implemented in 1992, was the physician work component, the payment for the physician's time and effort to provide the service. Beginning in January 1999, resource-based payments were incorporated for the practice expense component, which compensates physicians for the costs incurred in operating their practices.

The development of the resource-based practice expense component was a substantial undertaking. It began with an estimate of each physician specialty's total practice expenses and then used information gathered from expert panels to allocate those expenses to individual services. Because of limitations in the available data and concerns about the payment rates established for some services, HCFA made adjustments to the data and the basic methodology. In an earlier report, we noted that the basic methodology was reasonable and a good starting point in establishing resource-based practice expense payments. Although each of the data sources used in the basic methodology has limitations, the data

¹In June 2001, HCFA's name was changed to the Centers for Medicare and Medicaid Services (CMS). This report refers to the agency as HCFA when discussing actions taken before the name change and as CMS when discussing actions taken since the name change.

²42 U.S.C. 1395w-4.

¹Practice expenses include rent, utilities, equipment, supplies, and the salaries of nurses, technicians, and administrative staff.

⁴Although the fee schedule includes a single payment for every service, each payment has three components—physician work, practice expense, and malpractice. This report refers to the practice expense component of payments as "practice expense payments." See *Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term* (GAO/HEHS-99-30, Feb. 24, 1999).

remain the best available for deriving service-specific practice expense estimates. However, we recommended that HCFA conduct sensitivity analyses to identify issues with the methodology that have the greatest effect on payments and that it target additional data collection and analysis efforts to address these issues.

The implementation of the resource-based methodology has been the subject of considerable controversy, partly because of HCFA's adjustments to the underlying data and basic method and partly because payment changes were required to be budget-neutral—which means that total Medicare spending for physician services was to be the same under the new payment method as it was under the old one.⁶ As a result, if Medicare payments to some specialties increased, payments to other specialties had to decrease. In fact, such redistributions have occurred, prompting concern from various specialties that their revised practice expense payments are too low. Oncologists (cancer specialists) claim that their practice expense payments are particularly inadequate for certain office-based services, such as chemotherapy administration.

For several years, considerable attention has been focused on Medicare payments for covered drugs related to a physician's services, such as cancer chemotherapy. HCFA initiated steps in September 2000 to lower these payments based on investigations that revealed that Medicare's payments were much higher than the actual acquisition costs of these drugs. This would have substantially reduced revenues to oncologists. Although in November 2000 HCFA suspended its efforts to reduce Medicare's drug payments, there continues to be interest in lowering Medicare's payments for covered drugs, including chemotherapy drugs.

In light of these concerns, the Congress directed us to conduct three studies. A report on one study, issued in September 2001, examined Medicare's payments for drugs. We concluded that Medicare's method for establishing drug payments is flawed and that Medicare payments far

⁵⁴² U.S.C. 1395w-4 (d).

⁶Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost (GAO-01-1118, Sept. 21, 2001). This report was mandated in section 429 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Appendix F, 114 Stat. 2763, 2763A-522).

exceed widely available prices to providers. The other studies focus on Medicare payments under the physician fee schedule, one related specifically to oncology services and one related to the data used to establish payments for all specialties. In this report, we have examined the practice expense component of the Medicare fee schedule, and in particular payments for oncology services. Specifically, we have analyzed (1) the effects of HCFA's application of the practice expense payment methodology on overall payments to oncologists and other specialties and (2) how adjustments that HCFA made to the basic practice expense payment methodology affected payments for specific services provided by oncologists. The third study, which is underway, will examine issues related to the adequacy of the data used to establish practice expense payments under Medicare's physician fee schedule for all specialties and ways the Centers for Medicare and Medicaid Services (CMS) can improve the data.

To conduct the work for this report, we reviewed the methodology that HCFA used in computing resource-based payments and had extensive discussions with its staff. We also met with representatives from the American Society of Clinical Oncology (ASCO) and oncology practices to obtain their views on the practice expense methodology and interviewed oncology researchers to discuss current chemotherapy administration practices. We estimated the effect of various adjustments HCFA made in computing payment amounts, and we estimated the effect of potential adjustments using the data that HCFA had used. We did not test the validity of these data or gather new data on physician practice expenses. Because the fee schedule methodology is such that changes in the payment rate for a single service affects the payment rates for all other services, we examined the impact of the adjustments on the payment rates for all services provided by all specialties. (For a more complete discussion of our scope and methodology, see appendix I.) We performed

⁷Our study found that Medicare's payments for physician-billed drugs were at least \$532 million higher than providers' acquisition costs in 2000. *Medicare Part B Drugs: Program Payments Should Reflect Market Prices* (GAO-01-1142T, Sept. 21, 2001).

⁶The study was mandated in section 213 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (P.L. 106-113, Appendix F, 113 Stat. 1501, 1501A-350).

⁹The study was mandated in section 411 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Appendix F, 114 Stat. 2763, 2763A-508).

our work from September 2000 through September 2001 in accordance with generally accepted government auditing standards.

Results in Brief

Oncology's practice expense payments in 2001 are 8 percent higher than they would have been had charge-based payments continued. Oncology's practice expense payments compared to their estimated practice expenses are about the same as the average for all physicians. Oncology representatives continue to have concerns that the data HCFA used and the adjustments it made result in their practice expenses, and consequently their payments, being understated. For example, HCFA appropriately reduced oncology's reported supply expenses to exclude the cost of drugs, which are paid for separately, before calculating practice expense payments. However, HCFA based its reduction on average physician supply expenses rather than on oncology's supply expenses. An adjustment based on oncology-specific information may result in higher payments to oncologists. Addressing other data and methodological issues raised by oncologists would have an uncertain impact on oncologists' payments under the fee schedule. Payment levels are determined by allocating the budget neutral target for physician spending among services according to the relative amounts of resources each service requires. More current or precise information for all specialties could increase, decrease, or leave unchanged estimated practice expenses for oncology services relative to the expenses of other specialties. Payments would change accordingly.

HCFA used an alternative methodology to establish practice expense payments for certain services that substantially reduced payments for some oncology services while raising payments for some of oncology's other services. The agency implemented the alternative method to correct perceived low payments for services that do not involve direct physician participation, such as many chemotherapy administration services. This alternative method relies on historical physician charges—rather than the expert panel estimates of the resources needed for each service—to allocate practice expenses across services. HCFA indicated that the expert panel estimates may have been inaccurate for nonphysician services. HCFA has allowed all medical specialties to choose whether to use the basic or the alternative method for determining payments for their nonphysician services, further affecting payments. For over 40 percent of nonphysician services, including many chemotherapy services, these modifications reduced rather than increased payments. At the same time, payments for many services with direct physician involvement increased.

Moreover, in adopting the alternative method, HCFA has not addressed the inappropriate allocation of indirect expenses to all services.

To ensure that practice expense payments better reflect differences in the costs of providing services, we are recommending that the Administrator of CMS examine the effect of the adjustments made to the basic methodology on average fees across specialties and classes of services, including the adjustment to oncologists' reported medical supply expenses; improve the allocation of indirect expenses across all services; and calculate payments for services without direct physician involvement using the basic method and, if necessary, validate the underlying resource-based estimates of direct practice expenses for all nonphysician services.

CMS, the American Medical Association (AMA), and ASCO provided us with written comments on a draft of this report. CMS agreed with our findings and acknowledged the importance of improving the oncology supply expense estimate and evaluating the indirect cost allocation method and the impact of the alternative method for calculating payments for nonphysician services. However, it indicated that it will not change the way it calculates practice expense payments until better approaches are identified. The AMA and ASCO both disagreed with our findings and recommendations. Both organizations raised concerns about the scope of our analyses and report and our use of existing data to analyze the adequacy of oncology payments.

Background

The Medicare physician fee schedule has three components. The first, the physician work component, provides payment for the physician's time, skill, and training required to provide a given service. The second, the practice expense component, reflects the expenses incurred in operating a practice, such as rent; utilities; equipment; supplies; and the salaries of nurses, technicians, and administrative staff. Finally, the malpractice component establishes payments for the costs of obtaining professional liability coverage. In 1999, the three components accounted for approximately 55 percent, 42 percent, and 3 percent, respectively, of the average fee.

Payments for the physician work component were the first to be converted from being charge-based to resource-based, beginning in 1992. Using specialty-specific physician expert panels, physician time and effort

in providing various services were estimated and used to establish payments for this component. In 1999, the practice expense component began to be paid under a resource-based methodology. Resource-based payments for the third component, malpractice expenses, were implemented a year later. The resource-based payments were required to be budget neutral with respect to the former payment method, meaning that Medicare's aggregate payments to physicians could not change as a result of the implementation of the new methodology.

Medicare's physician payment system ranks services on a common scale based on the relative amount of resources needed to provide each service, and then makes payments for each service proportional to those resources. The need to estimate and rank practice expenses for thousands of medical services presents enormous challenges. Most physicians' practices have readily available data on their costs, such as wages for administrative and clinical staff and the costs associated with rent, electricity, and heat. However, Medicare pays physicians by service, such as for a skin biopsy or a stress test, so CMS needs to estimate the portion of total practice expenses associated with each service—data that are not readily available.

The task of estimating practice expenses is made more difficult because there is considerable variation in practice expenses among specialties. This variation is likely due to historical differences in practice styles, the mix of services provided, and the setting in which services are provided. For example, physicians in some specialties may provide almost all services in their offices, thus incurring all of the expenses associated with providing the service, including medical equipment, technicians, and medical supplies. Physicians in other specialties may deliver most of their services at a hospital, thus incurring only expenses such as rent, administrative labor, and general office equipment. A physician in a solo practice is also likely to have practice costs different from those of a physician in a group practice. As a result, practice expenses, even for the same service, can vary considerably by specialty or by physician practice.

The effect of both problems—the difficulty in allocating practice expenses to services and the variation in expenses across practices—is mitigated

 $^{^{\}rm 10}{\rm The}$ resource-based practice expense component is being phased in over 4 years, from 1999 through 2002.

¹¹P.L. 103-432, Sec. 121, 108 Stat. 4398, 4408 (1994).

somewhat because Medicare's fee schedule payment for each service is based on the service's cost relative to all other services. Even though the actual expenses associated with a service cannot be precisely measured and vary across physicians' practices, the cost of one service relative to another is easier to estimate and is likely to vary less across practices.

Medicare recognizes over 65 different physician specialty groups, such as internal medicine, cardiology, and oncology. Specialties differ in the types of services they provide. Most specialties provide evaluation and management (E&M) services (for example, an office visit for an established patient) that make up almost half of physician services provided to Medicare beneficiaries. However, only certain specialties generally provide each of the remaining physician services—for example, cardiologists, general internists, and family practitioners provide the majority of electrocardiogram services. A small share (5 percent) of services, though billed by physicians, do not involve a physician's time because they are performed by nurses or other clinicians—services such as the drawing of blood or administration of certain chemotherapy treatments.¹² These services are referred to in this report as nonphysician services.

Basic Method for Determining Resource-Based Practice Expense Payments The basic methodology for developing resource-based payments for practice expenses has three steps. ¹³ First, each specialty's total practice expense pool—that is, the total costs that physicians in that specialty incur to operate their practices—is estimated. Second, this practice expense pool is allocated to the services provided by that specialty, based on estimates of the resources required to deliver each service. This results in an estimate of practice expenses for each service provided within each specialty. Third, when the same service is provided by more than one specialty, an average of those specialties' expenses for the service is computed. A final adjustment is made so that total physician payments are budget neutral—that is, the same as they would have been under the

¹²Some specialties, for example oncology and allergy/immunology, have a higher proportion (a third to half) of nonphysician services in their mix of services.

¹³Additional details on earlier payment proposals and refinements can be found in our earlier reports. *Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments* (GAO/HEHS-98-79, Feb. 27, 1998) and *Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term* (GAO/HEHS-99-30, Feb. 24, 1999).

previous payment system. (See appendix II for a more complete discussion of the basic methodology).

Each specialty's total practice expense pool was derived from 1995-through-1998 practice expense data collected by the AMA's Socioeconomic Monitoring System (SMS) survey and from Medicare physician billing data. From the SMS survey, the average expense per hour of physician time were calculated for each of six expense categories, clinical labor (nurses and medical technicians), medical equipment, medical supplies, administrative labor (such as an office manager or billing clerk), office expenses (such as rent and utilities), and other expenses. These hourly expense estimates were multiplied by the total hours spent by all physicians in each specialty treating Medicare beneficiaries (information obtained from Medicare billing data) to estimate each specialty's total practice expense pool.

HCFA convened 15 expert panels comprising physicians, nurses, and practice administrators to estimate the practice expense resources needed for specific services. Based on these service-specific resource estimates, practice expenses that are regarded as direct—clinical labor, medical equipment, and medical supplies—are allocated to particular services based on estimates of the quantity and cost of these resources required to provide each service. The indirect expenses, or overhead—administrative labor, office expenses, and other expenses—are allocated to specific services in proportion to the direct expenses and physician work involved in providing each service. Thus, a service that requires high direct costs (such as the use of an expensive, dedicated piece of equipment) or that has a high physician work value, indicating that it is a time-consuming or complex service, would have relatively high indirect costs.

As required by law, the Medicare physician fee schedule must establish a single value or fee for each service, regardless of which specialty provides it. ¹⁵ Consequently, when more than one specialty provides a service, an average is computed based on the frequency with which each specialty provides that service. As a result, specialties that perform a service more

¹⁴Indirect expenses are between 55 and 90 percent of total practice expenses, depending on the specialty. For oncology, indirect expenses are approximately 60 percent of their total practice.

¹⁵⁴² U.S.C. 1395w-4 (c) (2) (A) (i).

frequently have more influence over establishing the fee for that service than specialties that rarely perform it.

Adjustments to Basic Resource-Based Method

To compensate for potential shortcomings in the basic methodology and limitations in the data used to establish payments. HCFA made several adjustments to the specialties' practice expense pools and the method for calculating the payment rates for individual services. In response to concerns from various specialties regarding perceived low payments for nonphysician services, such as certain chemotherapy administration services, HCFA developed an alternative method to calculate payments for these services. The alternative method creates a separate practice expense pool for all nonphysician services and then allocates the practice expense pool using historical charges rather than the expert panels' estimates of the resources required for each service. 16 Recognizing that this alternative method did not always increase payments for the targeted services. HCFA allowed all specialties (in the second year of implementation of the resource-based practice expense payments) to identify individual nonphysician services that would "opt-out" of the alternative methodology and have payments determined using the basic methodology for all physician services. Several specialty societies requested that HCFA calculate payments for some or all of their specialties' nonphysician services under the basic method, and all such requests were granted. (See appendix III for a discussion of the alternative method for estimating practice expenses for nonphysician services.)

An adjustment specific to oncologists' practice expense estimates substituted the average medical supply expenses reported by all physicians for those expenses oncologists reported in the SMS survey. An adjustment was necessary because the oncologists' reported supply expenses included the costs of drugs administered in physicians' offices, most notably chemotherapy drugs, which are reimbursed separately. In the first year, the adjustment reduced the supply expense reported by oncologists from \$87.20 per physician hour to \$7.20—the supply expense of the average physician specialty—to avoid paying twice for drugs.

In its ongoing efforts to improve payments, CMS receives recommendations from the Practice Expense Advisory Committee (PEAC) for refinements to direct practice expense estimates for specific services,

 $^{^{16}}$ HCFA used historical charges as the allocators for nonphysician services because its analyses indicated that the panel estimates for these services were inaccurate.

and it has implemented many of these refinements.¹⁷ The agency has also made changes to its estimates of specialties' practice expense pools based on supplemental practice expense survey data submitted by some specialties. In accordance with recent legislation, all physician specialties may submit supplemental data to CMS, and the agency is required to consider these data in updating the physician fee schedule.¹⁸ As of August 2001, three specialty societies have done so.¹⁹

Oncology Fares As Well As the Average Specialty, Although Data Concerns Remain

The implementation of the resource-based practice expense payments did, as expected, result in a redistribution of payments across specialties with some specialties' payments increasing and others decreasing. Oncology's practice expense payments in 2001 are 8 percent higher than they would have been had the charge-based fee schedule continued in 2001. Oncology has fared at least as well as the average specialty under the new fee schedule, in that its payments equal about the same share of estimated practice expenses as the average for all specialties. Nonetheless, oncologists have expressed concern that their payments are too low because of certain adjustments HCFA made to the basic methodology and inadequacies in the survey data used to estimate practice expenses. However using higher estimates of oncology's medical supply expenses would have only a modest impact on oncology payments because the alternative method is used to calculate payments for nonphysician services. Potential future improvements in the practice expense data may affect estimated expenses for other specialties as well. Because the fees are established to reflect the relative costs of services across specialties, it is not clear whether payments to oncologists would increase, decrease, or stay the same with changes to the underlying data.

¹⁷The PEAC is a subcommittee of the AMA's Relative Value Update Committee (RUC), a panel of physicians with representatives from all of the major physician specialty societies that meets regularly and makes recommendations to CMS on the resources required to perform services.

 $^{^{16}}$ Section 212 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (P.L. 106-113, Appendix F, 113 Stat. 1501, 1501A-350).

¹⁹Data were submitted by the American Association of Vascular Surgery and the Society for Vascular Surgery and were accepted by CMS. Data were also submitted by the American Physical Therapy Association, but CMS indicated that the data were imprecise, so they were not used.

Resource-Based Practice Expenses Increased Oncologists' Payments Oncology is among the specialties that benefit from resource-based practice expense payments. Its practice expense payments are 8 percent more than they would have been had the charge-based fee schedule continued in 2001 (see table 1). Although other specialties' payments are also higher than they would have been had the previous system remained in effect, many specialties' practice expense payments are lower. For example, dermatology's resource-based practice expense payments are 46 percent higher than what they would have been under the charge-based system. Other specialties' practice expense payments decreased, ranging from 9 percent to 35 percent less than what their practice expense payments would have been under the charge-based system. Total payments calculated with resource-based practice expenses ranged from 20 percent higher than total payments calculated with charge-based practice expenses to 17 percent lower.

Table 1: Comparison of Estimated Physician Payments Calculated with Resourcebased Practice Expense Payments and Charge-based Practice Expense Payments, 2001

, , , , , , , , , , , , , , , , , , , ,	Practice expense	· · · · · · · · · · · · · · · · · · ·
Specialty	payments (ratio)	Total payments* (ratio)
Dermatology	1.46	1.20
Obstetrics and gynecology	1.24	1.10
Urological surgery	1.21	1.09
Allergy and immunology	1.20	1.14
Otology, laryngology, rhinology	1.19	1.09
Ophthalmology	1.17	1.08
General family practice	1.17	1.07
Plastic surgery	1.13	1.05
Pediatrics	1.09	1.04
Oncology	1.08	1.04
Psychiatry	1.05	1.01
Orthopedic surgery	1.03	1.02
Neurology	1.02	1.01
Radiation oncology	1.02	1.01
General internal medicine	1.00	1,00
Radiology	.91	.95
Pathology	.90	.96
General surgery	.90	.96
Pulmonary disease	.85	.94
Cardiovascular disease	.79	.89.
Neurological surgery	.74	.88.
Emergency medicine	.66	.90
Gastroenterology	.65	.84
Cardio-thoracic, vascular surgery	.65	.83

Note: 1999 Medicare utilization data were used to estimate practice expense payments. Chargebased payments were based on the 1998 fee schedule, inflated to reflect 2001 spending levels. When resource-based practice expense payments equal charge-based practice expense payments, the ratio will be 1.00.

*Only the practice expense component of the total charge-based payment is based on charges.

Source: GAO analysis of practice expense payments under the Medicare fee schedule for 2001.

The budget neutrality requirement results in practice expense payments on average equaling approximately 70 percent of estimated practice expenses. However, payments equal different shares of estimated practice expenses for different specialties (see table 2). Payments are a smaller share of practice expenses for those specialties with higher-than-average hourly practice expenses and a larger share of expenses for specialties with below-average hourly expenses. This is primarily because of the

statutory requirement that there be a single fee for each service regardless of which specialty provides it. A single fee for each service is calculated by averaging the service-specific practice expense estimates of the specialties that perform the service. This requirement has a substantial impact on many specialties' payments, in part because E&M services, which are provided by most specialties, constitute a large share of many specialties' services.

Table 2: Comparison of Total Estimated Practice Expense Payments and Estimated Practice Expenses, Relative to the Average Across All Specialties, 2001

Specialty	Payments compared to practice expenses* (ratio)
Radiology	1.54
Allergy and immunology	1.43
Radiation oncology	1.28
Emergency medicine	1.17
Pulmonary disease	1.16
Psychiatry	1.06
General surgery	1.04
Internal medicine	1.04
Oncology	1.04
Pediatrics	1.02
Average (all specialties)	1.00
General family practice	.99
Urological surgery	.97
Gastroenterology	.96
Obstetrics and gynecology	.96
Otology, laryngology, rhinology	.94
Dermatology	.94
Cardiovascular disease	.93
Neurology	.91
Neurological surgery	.88.
Ophthalmology	.84
Orthopedic surgery	.84
Cardio-thoracic, vascular surgery	.76
Pathology	.75
Plastic surgery	.65

Note: 1999 Medicare utilization data were used to estimate practice expense payments. When estimated practice expense payments equal estimated practice expenses, the ratio will be 1.00.

Source: GAO analysis of practice expense payments under the Medicare fee schedule for 2001.

^{*}Each specialty's payments relative to its practice expenses are compared to the average for all specialties.

Medicare payments to oncologists equal about the same share of estimated practice expenses as the average for all specialties. Compared to oncology, 6 specialties had practice expense payments that equaled a larger share of their estimated practice expenses, while 15 specialties had practice expense payments that equaled a smaller share. Payments to two specialties, radiology and allergy and immunology, equaled a much larger share of their estimated practice expenses compared to other specialties.

Oncologists Express Concerns About Practice Expense Method and Data

Oncology representatives have raised several concerns about HCFA's estimate of their total practice expenses. HCFA reduced oncology's practice expense pool to account for the costs of drugs that are reimbursed separately. Oncology representatives acknowledge that a reduction is appropriate but state that the all-physician average supply expense that HCFA substituted understates oncology's supply expenses. In our earlier report, we noted this concern and recommended that HCFA assess the validity of using the all-physician average. To date, CMS has not developed an independent estimate of oncologists' supply expenses. An alternative estimate of supply expenses based on a methodology proposed by ASCO yields an estimate almost twice as high (\$13.25) as the 2001 all-physician average (\$7.30). Using this higher estimate, oncology's practice expenses would increase 6 percent and practice expense payments based on this estimate would increase 1 percent.

Some oncologists we spoke with have raised other issues that they believe caused their practice expense pool to be underestimated. The first is that only physician time is used to estimate the practice expense pools. HCFA estimated the practice expense pools by multiplying the number of physician hours spent serving Medicare patients by the estimated practice

²⁰Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

²¹Data supplied by a national oncology practice management company indicated that their actual medical supply expenses are higher than the current all-physician average. These data, however, are not representative of all oncology practices.

²²Payments do not go up as much as expenses for two reasons. First, the nonphysician service payments, calculated under the alternative methodology, are based on average hourly expenses across all specialties, so a higher estimate of oncology supply expenses does not change the payment amount for about one-third of the services oncologists provide. Second, payments for E&M services (which represent two-thirds of oncology services) are determined by the average E&M practice expenses across all specialties and, because oncology is a small specialty, its actual expenses have a limited effect on the average payment calculation.

expense per physician hour. The method HCFA used to calculate the practice expense per physician hour, however, results in an estimate that captures the expenses associated with both physician and nonphysician services rather than just the expenses associated with physician services. Therefore, what some oncologists believe to be understated hours are used with expenses associated with physician plus nonphysician services to estimate the total practice expense pool. As a result, the pool may not be understated.

Some oncology representatives believe that their practice expense estimates are too low because they do not account for certain expenses incurred in operating a practice, such as the time spent providing uncompensated care and extended periods of patient monitoring. Some also believe Medicare patients are more expensive to treat than the average patient due to their age and the increased presence of multiple medical conditions, implying that a higher share of expenses should be allocated to Medicare. Finally, some oncology representatives believe that their current expenses are higher than those included in the 1995-through-1998 SMS survey data due to changes in the delivery of outpatient chemotherapy services. Although clinical time spent on non-billable activities, more expensive-than-average patients, or changing practice patterns could affect oncologists' practice expenses, accounting for these factors would not necessarily raise payments to oncologists. This is because these factors are likely to affect the total practice expenses of other specialties as well. Payments to oncologists would only change if their costs increased or decreased relative to the costs of all other specialties.

Some oncology representatives also state that the SMS survey does not accurately reflect the mix of oncology practices and, as a result, their practice expense pool is underestimated. They contend that the 34 oncology respondents to the SMS survey are not representative of the typical practice because the survey respondents were disproportionately in practices that do not provide chemotherapy services in their offices. Because these practices do not incur the direct costs (such as nursing, equipment, and supplies) associated with these services, they argue that a disproportionate share of these practices in the sample led to an underestimation of oncology practice expenses. They also assert that the survey respondents included some surgical oncologists, a subspecialty that provides little or no office-based chemotherapy—again leading to an understatement of the practice expenses incurred by the typical practice. Although the AMA weights the sample responses to adjust the survey

results so they are representative of an entire specialty, ASCO contends these adjustments are inadequate.

The effect on payments to oncologists of using updated or more accurate data to estimate practice expenses is uncertain, but potentially modest. This is because the estimates of the practice expenses for other specialties and other services may change as well. Payment levels change when the estimated practice expenses of one specialty change relative to the overall average. Thus, the change in oncologists' payments will depend on how much estimated practice expenses for oncology increase or decrease compared to practice expenses for other specialties. In addition, the use of the alternative method to calculate practice expense payments for nonphysician services mitigates the impact of any change in the data on the resulting payments. Our analysis indicates that if estimated practice expenses for oncologists were increased or decreased 10 percent from their current estimates, their practice expense payments would only increase or decrease by 1 percent. The change in payments is less than the change in estimated expenses because under the alternative practice expense method, which determines payments for a large share of oncology services, oncology's actual practice expense estimates do not determine the payment.

Alternative Method Results in Large Changes in Payments for Many Oncology Services To correct for perceived low payments for services that do not involve direct physician participation (such as many chemotherapy administration services), HCFA created an alternative method to establish practice expense payments for these services. Contrary to the intended purpose, payments for over 40 percent of nonphysician services provided by all specialties actually decrease after the alternative method is applied, and payments for many physician services increase. Payments for some chemotherapy administration services decline, and oncology's average payments are actually lower than they would be if payments for all services were calculated under the basic method. Other specialties fare differently—for example, payments to radiation oncology are considerably higher as a result of the alternative method. This alternative method does not address the more fundamental issue affecting payments for nonphysician services, the allocation of indirect expenses to all services.

Alternative Method for Calculating Payments for Nonphysician Services Alters Resource-Based Fees Four elements of the alternative method developed by HCFA to correct for perceived underpayments for nonphysician services (including chemotherapy administration) affect the relative payments for oncologists as well as other specialties. First, the alternative method involves creating a single practice expense pool for all nonphysician services provided by all specialties, so differences in practice expenses across specialties are not recognized, as they are under the basic method. Thus, payments for services, such as chemotherapy administration, that are provided predominately by higher-cost specialties are lower than they would be if specialty-specific expenses were used to estimate payments for these services. Second, the expense pool is allocated to individual nonphysician services based on average historical charges for each service, rather than on the expert panels' estimates of the resources needed for each service. For some services, the charge-based allocations are higher than the expert panels' estimates: for others, they are lower. Third, HCFA subsequently allowed any specialty to choose whether or not the alternative method would be used for their particular nonphysician services. As specialties choose to have payments for certain nonphysician services computed using the basic method, the fees for all the other nonphysician services may increase or decrease.²³ Finally, the expenses associated with the nonphysician services are double counted because they were not taken out of the specialty-specific practice expense pools when the nonphysician practice expense pool was established. The resulting specialty-specific practice expense pools were too high because they included expenses for physician and nonphysician services, yet they were allocated only to the physician services. As a result, payments for some physician services increased.

While intended to counter perceived low payments for nonphysician services under the basic method, the alternative method resulted in higher payments for only 58 percent of nonphysician services, compared to payments under the basic method. For example, the practice expense fee for one chemotherapy service (billing code 96400) would be \$59.60 under the basic method, but decreases to \$5.07 under the alternative method (see table 3). In contrast, the practice expense fee for a chemotherapy infusion service (billing code 96412) increases from \$31.32 to \$43.11. The use of the alternative method also has a dramatic effect on payments for some

²³In 2001, payments for nonphysician services that continued to be paid under the alternative method were 4 percent lower than they would have been had no nonphysician services opted out of this methodology.

physician services due to the double counting problem. For example, payment for chemotherapy intracavitary service (billing code 96445), which involves a physician's direct time, increases from \$148 to \$316.

Table 3: Estimated Practice Expense Payments Calculated Under the Basic and Alternative Methods for Selected Nonphysician and Physician Services, 2001

	Estimated practice expense payments		
Service description (billing code)	Using Basic method	Using alternative method for nonphysician services	Difference between basic and alternative method
Nonphysician Services			
Chemotherapy, subcutaneous or			
intramuscular (96400)	\$56.90	\$5.07	-91%
Injection, (90782)	8.43	3.99	-53
Chemotherapy, push technique (96408)	48.22	36.23	-25
Chemotherapy, infusion method (96410)	70.10	57.97	-17
Intravenous infusion therapy, 1 hour (90780)	47.54	41.66	-12
Immunotherapy, one injection (95115)	13.86	14.49	5
Chemotherapy, infusion method add-on (96412)	31.32	43.11	38
Injection, intravenous (90784)	11.29	17.75	57
Physician Services			
Bone biopsy, trocar/needle (20220)	96.54	181.95	88
Chemotherapy, into central nervous system (96450)	128.09	255.43	99
Set radiation therapy field (77290)	124.70	263.48	111
Chemotherapy, intracavitary (6445)	148.14	315.53	113
Bone marrow aspiration (85095)	77.07	168.67	119

Note: 1999 Medicare utilization data were used to estimate practice expense payments. All payments are for services performed in a physician's office. The basic method is used to calculate practice expense payments for all physician services. The alternative method is used to calculate practice expense payments for nonphysician services.

Source: GAO analysis of practice expense payments under the Medicare fee schedule for 2001.

Payments for oncology's nonphysician services are 15 percent lower when calculated under the alternative method than when calculated under the basic method, while payments for its physician services are 1 percent higher (see table 4). Across all oncology services, payments are 6 percent

lower when the alternative method is used.²⁴ Payments to other specialties that have a large share of nonphysician services are affected differently. For example, payments for the nonphysician services provided by allergy and immunology specialists are 13 percent lower when using the alternative method, while payments for nonphysician services of radiation oncologists are 14 percent higher. Payments for the physician services of both specialties increase considerably as a result of the alternative method—by 16 percent for allergy and immunology and 20 percent for radiation oncology.

Table 4: Estimated Effect of the Alternative Method on Practice Expense Payments Compared to the Basic Method, for Selected Specialties, 2001

Specialty	Nonphysician services	Physician services	All services combined
Oncology	-15%	1%	-6%
Allergy immunology	-13	16	2
Otology, laryngology, rhinology	5	0	0
Radiation oncology	14	20	17

Note: 1999 Medicare utilization data were used to estimate practice expense payments. More than 25 percent of the services of these specialties are nonphysician services. The basic method is used to calculate practice expense payments for all physician services. The alternative method is used to calculate practice expense payments for nonphysician services that continue to be paid under this method.

Source: GAO analysis of practice expense payments under the Medicare fee schedule for 2001.

Recognizing the potential need to modify its practice expense methodology, HCFA contracted with The Lewin Group to examine practice expense payments and suggest improvements to the payment method. The contractor raised concerns that the expense pools of specialties with nonphysician services may be understated for two reasons. First, it stated that the practice expense estimates based on the SMS survey may underreport expenses for nonphysician services because practices that provide only nonphysician services (such as independent

²⁴We estimate that using the basic method for establishing payments for nonphysician services would have increased oncology's payments by \$31 million in 2001. Substituting the estimate of medical supply expenses for oncology based on the ASCO methodology would have raised payments to oncologists by an additional \$20 million in 2001 if payments were calculated under the basic method.

²⁵The Lewin Group, Inc., *The Resource-Based Practice Expense Methodology: An Analysis of Selected Topics* (Falls Church, Va., 2001).

laboratories and radiology centers) were not included in the survey and may have higher practice expenses. Second, it believed that the use of physician time in estimating the total practice expense pools could understate the estimate for specialties with nonphysician services, although it acknowledged that hourly practice expense estimates that include expenses related to nonphysician services may offset this. It also determined that indirect expenses are not appropriately allocated to nonphysician services.

The Lewin Group discussed the option of establishing payments for nonphysician services under the basic method after correcting the allocation of indirect expense for these services. It also stated that if CMS retains the alternative methodology, it should consider the option of establishing specialty-specific practice expense pools for nonphysician services, instead of the single pool, to account for the differing costs across specialties. However, the report did not consider the double counting issue, nor did it address the fact that payments for nonphysician services would continue to reflect historical charges rather than relative resources, as required by Congress. CMS said that it plans to evaluate these options and consider changes to its method for calculating nonphysician services.

Payments Relative to Estimated Practice Expenses Vary Considerably Across Oncology Services and Practices

While oncologists' average payments equal approximately the same share of estimated practice expenses as the average for all specialties, the relationship between payments and estimated practice expenses for different types of oncology services varies considerably (see table 5). The use of the alternative method for determining nonphysician service payments and the requirement for a single payment for each type of service across all specialties contribute to this variation. Payments for E&M services, which make up about two-thirds of oncologists' services, are much higher relative to estimated practice expenses than are payments for other services. In contrast, payments for nonphysician administered chemotherapy, which comprises about one-third of oncology services, are a significantly lower than average share of estimated expenses.

Table 5: Oncologists' Service Mix, Practice Expense Shares, and Estimated Practice Expense Payments Compared to Estimated Practice Expenses, 2001

Type of oncology service	Share of total services	Share of total practice expense	Payments compared to practice expense (ratio)*
Physician services, total	67.98%	36.61%	1.60
Evaluation and management	64.89	31.75	1.66
Physician chemotherapy	0.02	0.04	2.07
Other physician services	3.08	4.82	1.21
Nonphysician services, total	32.02%	63.39%	0.64
Chemotherapy administration	30.90	58.18	0.67
All other nonphysician services	1.11	5.21	0.34
All services	100.00%	100.00%	1.00

Note: 1999 Medicare utilization data were used to estimate practice expense payments and expenses. Practice expenses for nonphysician services were estimated using the basic methodology and a combination of direct expenses and time to allocate indirect expenses for all services. With these two exceptions, CMS' methodology was used to calculate practice expenses.

*The ratios in this table have been adjusted so that the average for all oncology services equals 1.00. Source: GAO analysis of practice expense payments under the Medicare fee schedule for 2001.

These variations in payments relative to expenses across types of services have implications for different practices and could affect the mix of services an oncology practice would provide. The practices of individual oncologists vary considerably in the mix of services they provide (see table 6). While E&M services composed 67 percent of oncology services in 1999, they made up 84 percent of the services provided by oncologists with small Medicare practices. Nonphysician services (predominantly chemotherapy administration) made up more than three times the share of total services for oncologists with large Medicare practices, compared with oncologists who had small practices.

Table 6: Mix of Nonphysician and Physician Services Provided by Oncologists, 1999

		Type of service	
Size of Medicare practice	Nonphysician services	Physician evaluation and management services	Other physician services
Largest practices	34%	63%	3%
Smallest practices	10	84	7
Average of all practice	29	67	4

Note: A practice represents each site where an individual oncologist provides services. Generally, when a physician provides services at multiple sites, those services will be reported separately. The largest physician practices are the top 25 percent of physician practices, by volume of Medicare services billed; the smallest practices are the bottom 25 percent of physician practices, by volume of Medicare services billed.

Source: GAO analysis of oncology services, based on HCFA's 5 percent sample of 1999 Medicare claims data.

Underlying Problem With Allocation of Indirect Expenses Needs Correction HCFA developed the alternative method for nonphysician services because it believed the practice expense payments for these services were too low, and they attributed this to possible inaccuracies in the expert panels' estimates of resources needed for these services. Regardless of the accuracy of the panels' expense estimates, the basic method for allocating indirect expenses for all services, which relies partly on physician work as the basis for allocation, does not adequately account for the indirect costs associated with nonphysician services. Because nonphysician services have no physician work associated with them, they are allocated a lower share of indirect expenses compared with services that are performed by physicians.

Methods for allocating indirect expenses, other than the current use of physician work plus direct expenses, could assign these costs more appropriately across all services. As we noted in a 1999 report, indirect expenses such as rent, utilities, and office space are more likely to vary with the time required to perform a service than with the physician's work, which also measures the level of skill required to perform the service. For nonphysician services, clinical time could be substituted for physician

 $^{^{26}63}$ Fed. Reg. 58,814, 58,821 (1998) (preamble to the final rule with comment period).

²⁷Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

work to allocate overhead expenses more appropriately. Using only direct practice expenses to allocate indirect costs is another option, but under the current fee schedule methodology this option would result in understating the indirect cost estimates for services provided in hospital settings and overstating the expenses for office-based services.

In its study of the practice expense methodology, The Lewin Group also examined the method of allocating indirect expenses.28 It compared practice expense estimates using different indirect cost allocation methods across broad groups of services and specialties. Its analyses showed that for these groups of services and specialties, practice expenses in most cases did not change much when the indirect allocation method was changed. Therefore, it concluded there is no consensus on an appropriate method for allocating indirect practice expenses and that CMS's current approach is reasonable. However, the comparisons did not consistently consider the effect of averaging the specialty-specific practice expense estimates to determine a single payment rate. Further, its comparisons indicated how much practice expense estimates changed relative to expenses estimated with the current indirect allocation method, which may not be an appropriate benchmark because it underallocates indirect expenses to nonphysician services and overallocates them to physician services. The effect of different allocation methods on nonphysician services was not assessed, even though the current method is problematic for them as well. Finally, it did not examine the effects of different allocation methods across individual specialties and services. even though the effects may have varied considerably.

Conclusions

The basic method for determining practice expense payments under the fee schedule establishes payments for individual services that are resource-based and reflect the relative costs of all services provided by all specialties. Practice expenses for most services are estimated using the best information available, including national data and expert assessments of the resources required to perform services. As we have reported before, because of limitations in the fee schedule methodology and the underlying data used to establish payments, the payment system needs to be analyzed thoroughly to determine how it can be improved.

²⁸The Lewin Group, An Evaluation of Health Care Financing Administration's Resource-Based Practice Expense Methodology (Falls Church, Va., 2000).

Our analysis of oncologists' estimated practice expenses and their payments indicates that oncology has fared as well under the resource-based fee schedule as it did under the former charge-based system and compared to other specialties. Yet oncology was disproportionately affected by the alternative method HCFA used to calculate payments for nonphysician services, which failed to address the underlying problem with the allocation of indirect expenses to all services. Further, the use of the all-physician average supply expenses in estimating oncology practice expenses is inappropriate without evidence regarding oncologists' actual supply expenses. Addressing these two problems is likely to increase practice expense payments to oncologists.

Other concerns oncology representatives raise about the adequacy of the practice expense data used to establish payments should also be dealt with. Addressing these underlying data issues, however, is likely to affect the practice expense estimates of other specialties as well, so the resulting effect on payments to oncologists is unclear. This is because payments reflect relative resource use across all specialties and services and payments must be budget neutral, meaning that increases and decreases are balanced so that total payments do not change from these kinds of adjustments. To ensure appropriate payments across all specialties and services, CMS needs to use current and accurate practice expense data for all specialties and refined service-specific expense estimates. The approach to obtaining these data needs to balance the need for valid, verifiable information with the administrative resources and provider burdens that collecting it may entail.

Just as more current and accurate data will affect payments for all services, refinements to the current practice expense methodology will also affect payments across all specialties and services. The widely varying effects of elements of the current fee schedule methodology on specialties and services underscore the importance of examining the effect of future refinements on payments in the aggregate, for individual specialties, and for individual services.

Recommendations for Executive Action

To ensure that practice expense payments for all services under the fee schedule better reflect the costs of providing services, we are recommending that the Administrator of CMS:

 examine the effects of adjustments made to the basic methodology across specialties and types of services and validate the appropriateness of these adjustments, including the adjustment made to oncologists' reported

- medical supply expenses, giving priority to those having larger impacts on payment levels;
- change the allocation of indirect expenses so that all services are allocated the appropriate share of indirect expenses; and
- calculate payments for all services without direct physician involvement under the basic method, using information on the resources required for each service, and, if deemed necessary, validate the underlying resourcebased estimates of direct practice expenses required to provide each service.

Comments From CMS and Others

We received comments from CMS, the AMA and ASCO on a draft of this report. The comments and our discussion are presented below.

CMS Comments

In comments on a draft of this report, CMS agreed with our general findings (see Appendix IV). CMS agreed that a better estimate of actual oncology supply expenses is needed and acknowledged the usefulness of reviewing indirect cost allocation methods and the importance of this allocation for practice expense payments. It also noted that the studies conducted by The Lewin Group to evaluate several different allocation options found no reason to change the current methodology. CMS also agreed that the alternative methodology used to calculate payments for nonphysician services needs further evaluation. It stated, however, that as an interim policy, the alternative methodology is serving its intended purpose and that changing it would redistribute payments across specialties. CMS did not indicate that it plans to implement our recommendations. It also provided a summary of its ongoing efforts to refine practice expense payments.

In agreeing that a better estimate of oncology supply expenses is needed, CMS indicated that it has suggested changes to the AMA's SMS survey instrument to improve the SMS data, with particular suggestions about supply expenses. A modified survey instrument is an appropriate step in improving the data, but there are no assurances that the AMA will implement these changes. Further, CMS has not indicated that it has any plans to examine the effects of all of the adjustments made to the basic methodology on payments across specialties and types of services. We believe this type of systematic evaluation, followed by targeted refinements to areas with a greater impact on payments, is necessary to improve practice expense payments.

In its comments, CMS said it would be useful to review the allocation of indirect expenses in establishing practice expense payments, and it asked The Lewin Group to do the review. The Lewin Group confirmed the problem with the current indirect allocation method. As two alternatives to improve the practice expense payment calculations, it proposed that CMS examine specialty-specific nonphysician practice expense pools or correct the indirect allocation method for nonphysician services and then return these services to the basic method. It acknowledged that any changes to practice expense payment calculations would result in higher payments for some specialties and lower payments for others, and it urged caution in implementing any changes. However, indirect costs are systematically under-allocated to nonphysician services and over-allocated to physician services. Further, the alternative method, which was intended to increase payments for nonphysician services, does not consistently do so and it inflates payments for some physician services. We believe that CMS should address these issues consistently across all services. We have added discussion of The Lewin Group studies to the body of our report.

CMS indicated that it does not intend to eliminate the alternative method for nonphysician services until it can identify and propose a better approach. Yet our analysis indicates that this interim approach violates congressional intent that payments be resource-based and significantly changes payments for some services. Oncology is one of the specialties that is disproportionately affected by the interim approach. An improved indirect allocation method—one that allocates an appropriate share of indirect expenses to all services, including nonphysician services, combined with calculating payments for all services under the basic method—would result in resource-based practice expense payments under Medicare's physician fee schedule that reflect the relative costs of providing each service. We believe that these improvements should be made, even though they will cause payment redistributions. CMS also made technical comments, which we incorporated as appropriate.

AMA Comments

In its comments, the AMA expressed concern about the scope of the report, questioning whether it provided enough information to the Congress regarding the adequacy of payments for outpatient cancer therapy. In this context, it had concerns about the range of physician groups we consulted and whether we had reviewed all relevant studies conducted for CMS. The AMA said it would have liked us to conduct a survey of oncologists' supply costs. The AMA also said that our discussion about how oncology has fared under the fee schedule relative to other specialties is inconsistent with our conclusion that oncology's concerns

about the data and methods underlying their payments should be addressed. The AMA also stated that it had "significant concerns" about our recommendations. Regarding our first recommendation that CMS examine the effects of all adjustments, the AMA pointed out that CMS had already simulated the effects of adjustments made to the basic method. With respect to our recommendation that the allocation of indirect expenses be changed, the AMA referred us to The Lewin Group studies. Finally, the AMA said that the nonphysician practice expense pool and ongoing refinement process precluded the need for other refinement efforts, as we discussed in our third recommendation.

To address the AMA's concerns about the scope of our report, we have added language to the report to make it clear that we were directed to conduct three related studies. The report on Medicare payments for drugs was issued in September 2001. A forthcoming report will examine issues related to the adequacy of the data underlying the practice expense payments and ways that CMS could improve these data. That study will necessarily involve discussions with and input from a variety of physician organizations as the AMA suggests. In the current report, we addressed the adequacy of Medicare practice expense payments for outpatient chemotherapy services using national data on practice expenses to reach our conclusions.

Our analysis and recommendations stress the need for ongoing examination and refinements to the data and methods underlying Medicare's practice expense payments, but this is not inconsistent with our conclusion that oncologists have fared as well as other specialties under the Medicare fee schedule. We agree with the AMA, that CMS has simulated adjustments to their basic methodology, but we believe these simulations should be used to focus on-going refinement efforts. As discussed earlier, we did consider the work conducted by The Lewin Group in our analysis and have added a more complete discussion of its work. We believe that all payments should be calculated under the basic method because this ensures that, as the Congress has directed, payments reflect the resource use of each service relative to all other services rather than historical charges. Finally, we agree that CMS' ongoing refinement process utilizing information supplied by the AMA is an appropriate way to identify refinements to service-specific resource estimates. Using this refinement process will be particularly important if payments for nonphysician services are established under the basic method because CMS has indicated that these resource estimates for nonphysician services need refinement.

ASCO Comments

In its comments, ASCO expressed concern about the scope of this report. ASCO's other comments fall into three broad categories. One set of concerns focuses on the quality, representativeness, and accuracy of the data used to establish practice expense payments and our use of these data in our analysis. A second set has to do with payments for nonphysician services, which ASCO acknowledges are problematic. Finally, ASCO is concerned that practice expense payments for nonphysician services do not fully cover their reported practice expense costs. It states that payments for physician work and drugs are needed to cover the practice expense payment shortfalls and that without payments that fully cover costs, oncologists may not provide chemotherapy services in office settings.

We have added language to the report to make it clear that we were asked to conduct three related studies, as noted in our response to the AMA's comments above. This report addresses the issues raised by the Congress regarding the adequacy of Medicare practice expense payments for outpatient chemotherapy services. Our report discusses the data concerns raised by ASCO and others. To illustrate the possible impact of underlying data limitations, we simulated the impact on payments of increased medical supply expenses and a 10 percent increase or decrease in practice expenses. Our conclusions and recommendations emphasize the importance of representative and reliable SMS data. Our analyses indicate that the alternative method of establishing practice expense payments for nonphysician services significantly changes payments for some services and that indirect expenses are not appropriately allocated across all services. The report includes a discussion of two ways of allocating indirect expenses, and we recommend changes to address the problems with the current method of calculating payments for nonphysician services. We also note that it is important to assess the effect of any refinements by examining changes in payments across all services and specialties. Finally, as we have noted, our prior work indicates that Medicare's payments to physicians for drugs far exceed the reduction in payments that result from the use of the alternative method used to calculate payments for nonphysician services.

We are sending copies of this report to the Administrator of CMS and interested congressional committees. We will also make copies available to others upon request.

If you have any questions about this report, please call me at (202) 512-7119 or Carol Carter, Assistant Director, at (312) 220-7711. Major contributors include Gerardine Brennan and Iola D'Souza.

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Jana a. Dummit

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Appendix I: Scope and Methodology

To conduct this work, we recreated the practice expense component of the fee schedule for 1999 and 2001 and analyzed the impact of the fee schedule on aggregate practice expense payments to all specialties and for individual services. Even though this report focuses on payments to oncologists, a thorough analysis must consider the entire practice expense payment approach because payments are intended to reflect relative cost differences across all services and specialties. We examined payments in 1999 because this was the first year of the transition from charge-based to resource-based practice expense values. We analyzed payments in 2001 because they reflect the most current fee schedule and include the most up-to-date refinements to the resource-based methodology. We also modeled payments under various other scenarios, which included: (1) assuming that the supply cost estimate for oncology was nearly double the current estimate (\$13.25 vs. \$7.30), (2) assuming that total practice expense cost estimates for oncology services were 10 percent higher or lower than current estimates for oncology, and (3) eliminating the separate methodology developed for nonphysician services.

To model practice expense payments we used several data sources, including the American Medical Association's Socioeconomic Monitoring System (SMS) survey and several data files required to calculate these payments for each of the years identified.¹ To estimate practice expense payments, the following files were used: the SMS survey results from 1995 through 1998; the Health Care Financing Administration's (HCFA) publicuse utilization files based on 1997 and 1999 claims; HCFA's publicuse physician-time files for 1999 and 2001; HCFA's publicuse clinical practice expert panel (CPEP) summary file for 1999 and 2001; the published physician fee schedules for 1998, 1999, 2000, and 2001; and files provided to us by HCFA that included imputed physician fee schedule values for anesthesia codes for 1998 through 2001. Consistent with the method used by HCFA as detailed in the *Federal Register*, several adjustments were made to the SMS data.

To estimate each service's practice expense in table 5, we used the Centers for Medicare and Medicaid Services'(CMS) basic methodology for calculating resource-based practice expense payments with two variations.² These variations were intended to account for weaknesses we

¹CMS provides detail on the data required to calculate the physician fee schedule practice expense payments on its Web site at the following address: http://www.HCFA.gov/stats/resource.htm.

²See appendix II for a detailed description of CMS' basic methodology.

Appendix I: Scope and Methodology

identified in the current nonphysician services payment approach. First, we did not use the alternative method to calculate payments for the nonphysician services—all services were calculated using the basic method. Second, to allocate indirect costs we used time—physician time for physician services and clinical time for nonphysician services—instead of physician work. As we noted in a 1999 report, indirect expenses such as rent, utilities, and office space are more likely to vary with the time required to perform a service than with the physician's work. Because the alternative methodology uses the all-physician average hourly expenses, it may not be a good estimate of the expenses incurred by oncologists.

The medical supply expense estimate of \$13.25 per physician hour was derived using a methodology suggested by the American Society of Clinical Oncology (ASCO). Using Medicare claims data, it estimated total drug costs for oncology of \$441 million and medical supply costs of \$79 million. These estimates suggest that medical supplies represent 15 percent of total supply costs for oncologists. Supply costs (including drugs and medical supplies) were estimated to be \$87.20 per physician hour using SMS data from 1995 through 1997. The medical supply portion would be equal to 15 percent of that, or \$13.25.

We estimated what 2001 charge-based practice expense payments would have been by using 1998 charge-based payment rates inflated to the 2001 spending levels.

To analyze the variation in the mix of chemotherapy and physician services provided by oncologists, we used 1999 Medicare physician claims data. We based our analysis on each physician's billing identification number, which is unique to each site where a physician provides services. This analysis allowed us to examine the mix of services for each physician billing from each practice site, but it did not tell us the mix of services for a given practice in which multiple oncologists provide services. Large physician practices were defined as the top quartile of service providers, by Medicare volume, and small physician practices were defined as the bottom quartile.

³Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

Appendix I: Scope and Methodology

Throughout this process we held discussions with CMS staff to clarify and confirm our understanding of their methodology. In addition, we met with representatives from ASCO and oncology practices to obtain their views on the practice expense methodology and interviewed oncology researchers to discuss current chemotherapy administration practices.

Appendix II: Overview of Medicare's Basic Practice Expense Method and Adjustments

This appendix details how the Health Care Financing Administration (HCFA) developed resource-based practice expense payments. Additional details on earlier proposals and refinements can be found in our earlier reports. 2

The Social Security Act Amendments of 1994 mandated that Medicare pay for physicians' practice expenses based on the cost of required resources. HCFA's method included three basic steps (see figure 1):

- 1. Estimating practice expense costs for specialties. Data collected in the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) survey were used to estimate specific practice expense costs for each specialty per physician hour. Estimates were made in three direct cost categories (clinical labor, medical equipment, and medical supplies) and three indirect cost categories (administrative labor, office expenses, and other expenses). The per hour estimates for each category were multiplied by the total number of hours in a year spent by physicians in that specialty on treating Medicare patients. The resulting total expenses for each cost category were added together to estimate each specialty's aggregate annual practice expenses, or "cost pool."
- 2. Allocating total expenses to individual services. The estimated total practice expense cost pool for each specialty was allocated to individual services that specialty performs. For direct costs, this allocation was done with estimates made by clinical practice expert panels (CPEP) convened by HCFA. These panels enumerated the direct resources (such as nursing time or medical supplies) that were

¹We relied largely on HCFA's June 5, 1998, proposed rule (63 Fed. Reg. 30,818) and November 2, 1998, final rule (63 Fed. Reg. 58,814). Other sources included 64 Fed. Reg. 59,380 (Nov. 2, 1999), 65 Fed. Reg. 44,176 (July 17, 2000), and 65 Fed. Reg. 65,376 (Nov. 1, 2000).

²Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments (GAO/HEHS-98-79, Feb. 27, 1998) and Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

³The total hours physicians spent treating Medicare patients were estimated by multiplying the volume of each procedure by the amount of time physicians require to perform each procedure and summing these for all procedures performed by a specialty. HCFA used 1999 Medicare claims data to estimate the volume of services in calculating 2001 practice expense payments. The estimated time a physician spends on each procedure is a component of the physician work relative value unit (RVU).

Appendix II: Overview of Medicare's Basic Practice Expense Method and Adjustments

> used to deliver each service. The panel estimates were calibrated to the direct expense pools estimated with the SMS data.

The total indirect cost estimates were allocated to individual services based on (1) the direct cost estimate for each service and (2) a measure of physician work involved in the service. These estimates were also calibrated to the total expense from the SMS data. Finally, direct and indirect cost estimates were added together to determine total practice expense values per service for a specialty.

3. Averaging different estimates for services performed by multiple specialties. Because different specialties often provide the same services, the specialty-specific practice expense payment estimates had to be combined to produce one payment per service. To do so, HCFA calculated a weighted average of the various estimates. Each specialty's practice expense estimate for a service was multiplied by the total number of times that specialty performed the service in a year. The results for all specialties were then added together. The sum was divided by the total volume of the services in a year by all specialties, and the result determined the final practice expense amount. In this way, specialties that perform a given service frequently have more influence over the payment than specialties that rarely perform it.

Adjustments to the Resource-Based Methodology

HCFA made several adjustments to the underlying data and modifications to the basic method to compensate for shortcomings in the basic methodology and limitations in the data used to establish payments and to update payments.

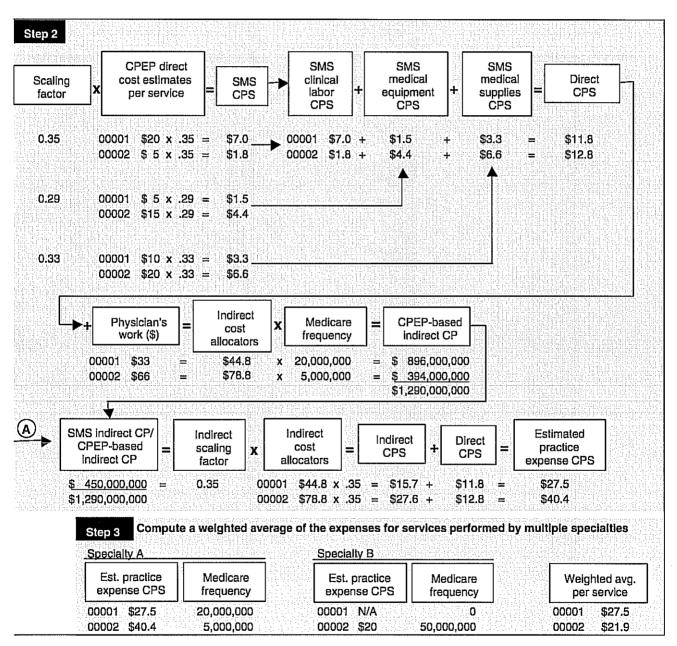
- 1. The physician specialty groups reflected in the SMS data were not the same as the physician specialty groups used by HCFA in establishing payments. The SMS reports practice expense estimates for 26 specialties, while HCFA used over 65 specialty categories. To create practice expenses for all 65-plus specialties, HCFA matched AMA data to its own specialty categories based on judgments about the best fit.
- 2. To address perceived low payments for nonphysician services, HCFA developed an alternative method to calculate payments for these services, using historical charge-based cost estimates, which it implemented in the first year of resource-based practice expense payments (see appendix III for a description of this alternative method). Recognizing that this alternative method did not always

increase payments for the targeted services, HCFA allowed specialties (in the second year of resource-based practice expense payments) to identify individual nonphysician services that would "opt-out" of the separate methodology and revert to having these services' payments set using the basic methodology for all physician services.

- 3. HCFA adjusted the payment rates for services that include both physician and nonphysician services in performing them. For example, an x-ray includes a nonphysician activity (taking and developing the film) and a physician activity (interpreting the film). These services can be billed together if both are performed in the same office, or separately, if each is performed at separate locations. To ensure that payments were equal, regardless of billing, it set the payment for the total service equal to the sum of the payments when billed individually.
- 4. In an ongoing effort to improve payments, HCFA receives from the Practice Expense Advisory Committee (PEAC) recommendations for refinements to direct practice expense estimates for specific services, many of which have been implemented.⁴
- 5. HCFA has made changes to its estimates of specialties' total expenses based on supplemental practice expense survey data submitted by the specialties, in accordance with the provisions of the Balanced Budget Refinement Act of 1999.

⁴The PEAC is a subcommittee of the American Medical Association's (AMA) Relative Value Update Committee (RUC), a multispecialty panel of physicians with representatives from all of the major physician specialty societies that meets regularly and provides comments on relative values to CMS.

Figure 1: Detailed Example of HCFA's Practice Expense Method for Physician Services Allocate Specialty A's total practice expenses to For Specialty A, estimate the average Step 2 Step 1 Individual services practice expenses for six different expense categories **CPEP** direct SMS Medicare **CPEP** cost estimates CP/ SMS cost pools frequency CP **SMS** practice per service CPEP expense CP Direct expenses estimates per Clinical physician hour 00001 \$20 x 20,000,000 \$400,000,000 \$150,000,000 labor 00002 \$ 5 5,000,000 \$ 25,000,000 \$425,000,000 Clinical \$150,000,000 \$425,000,000 labor \$15 Medical 00001 \$ 5 x 20,000,000 \$100,000,000 \$ 50,000,000 equipment 00002 \$15 x 5,000,000 \$ 75,000,000 \$175,000,000 Medical \$50,000,000 equipment \$175,000,000 \$5 Medical **▶** 00001 \$10 x 20,000,000 \$200,000,000 \$100,000,000 supplies Medical 00002 \$20 5,000,000 \$100,000,000 \$300,000,000 \$100,000,000 Total supplies \$300,000,000 physician \$10 hours treating X Medicare patients Indirect expenses Administrative 10,000,000 Administrative labor labor \$15 \$150,000,000 Office Office SMS indirect expenses expenses \$20 expenses CP \$200,000,000 \$450,000,000 Other Other expenses expenses \$10 \$100,000,000 CP Cost pool **CPEP** Clinical practice expert panel **CPS** Cost per service SMS Socioeconomic Monitoring System



Source: GAO Analysis.

Appendix III: Overview of Medicare's Alternative Method for Calculating Practice Expenses for Nonphysician Services

Physicians bill for services that involve little or no physician work and are performed by other staff. For example, many chemotherapy services are provided in a physician's office by a nurse or other health care professional and billed for by the physician. In response to provider concerns that payments for these nonphysician services were too low, HCFA developed an alternative method of calculating payments.

In the alternative methodology, the costs of nonphysician services were aggregated into what was called a "zero work" pool for all specialties. This, in effect created a new zero work specialty. The specialty-specific cost pools, however, were not reduced by the costs associated with the nonphysician services. Practice expense payments were then calculated for each of the nonphysician services, as they were for the other services, but with these notable deviations from the basic methodology:

- SMS data on average practice expenses for all physicians were used, instead of specialty-specific practice expense data, to calculate the nonphysician specialty's practice expense pool.
- Clinical time (including the time of nurses and other clinical personnel) was substituted for physician time in establishing the cost pool for these services.
- Direct costs were allocated across services based on historical charges, rather than the expert panels' estimates of service-specific resource requirements.
- Indirect cost allocations were based solely on charge-based direct cost estimates.

There was no need to average payments across specialties for the nonphysician services because only one payment is estimated for each nonphysician service.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services (formerly Health Care Financing Administration)

DATE:

OCT - 2 2001

TO:

Laura A. Dummit

Director, Health Care-Medicare Payment Issues

General Accounting Office

FROM:

Thomas A. Scully

SUBJECT:

General Accounting Office (GAO) Draft Report: Medicare Physician Fee

Schedule: Practice Expense Payments to Oncologists Indicate Need for

Overall Refinements (GAO-01-1125)

We appreciate the opportunity to review and comment on the above-referenced report.

GAO's draft report was completed in response to section 213 of the Balanced Budget Refinement Act of 1999. This section required the Comptroller General of the United States to conduct a nationwide study of the physician and non-physician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services. GAO concluded that oncologists have been advantaged by the change from a charge-based to a resource-based system of practice expense and have fared well relative to other specialties under the new system. We agree with this general finding.

In addition, GAO made three recommendations, which related to our methodology for determining resource-based practice expense relative value units.

GAO's recommendations and our response are as follows:

Recommendation:

Examine the effects of adjustments made to the basic methodology across specialties and types of services and validate the appropriateness of these adjustments, including the adjustment made to oncologists' reported medical supply expenses, giving priority to those having larger impacts on payment levels.

Page 2- Laura A. Dummit

Response:

We agree that the adjustment made for oncologists' reported medical supply expenses should be reviewed. We are considering how to best estimate more precisely the oncology supply practice expenses exclusive of drugs. Physician practice expense surveys are an important source of data for the practice expense methodology. On the survey we used to evalunte practice expenses, oncologists reported inordinately high practice expenses for medical supplies. The GAO indicated that adjusting the oncology medical supplies practice expense per hour, as we did, was necessary because the oncologists reported supply expenses included the costs of drugs administered in physicians' offices, most notably chemotherapy drugs, which are reimbursed separately. We welcome any data or suggestions that the GAO or the physician community could offer to help address this issue.

Recommendation:

Change the allocation of indirect expenses so that all services are allocated the appropriate share of indirect expenses.

Response:

We agree that it would be useful to review the allocation of indirect costs to specific services. Indirect expense allocation is one of the most significant issues for physician practice expense payments because indirect expenses (office space, billing costs, heat, phones, etc.) represent about two-thirds of total practice expenses. Therefore, different, yet plausible options can shift billions of dollars in Medicare payments among specialities. The situation is complicated because no universally accepted method for allocating indirect expenses exists, and a variety of approaches are compatible with standard accounting practices. In the June 18, 1997, Federal Register, we described why we chose to use a combination of physician work and direct expense to allocate indirect practice expenses.

As part of our refinement strategy, we contracted with the Lewin Group to assess a wide variety of practice expense refinement issues including options for allocating indirect expenses. In their September 6, 2000, report to us, the Lewin Group reviewed issues regarding indirect expense allocations and indicated that "... no other allocation methodology offers a compelling reason to abandon the current HCFA approach." While the Lewin Group did not recommend changing current policy, they have suggested ideas that may improve the allocation of indirect costs for specific services such as those that do not have direct physician involvement.

Page 3- Laura A. Dummit

We are currently analyzing the Lewin suggestions. If our analysis suggests that there is merit in modifying the indirect allocation methodology in conjunction with eliminating the special adjustments for non-physician services, under current law, we would propose a change through the rulemaking process to allow for public comment:

Recommendation:

Calculate payments for all services without direct physician involvement under the basic method using information on the resources required for each service, and if deemed necessary, reconvene expert panels to refine information on the resources required to provide each service.

Response:

We agree with the need to continue evaluating the special adjustment for services that do not have direct physician involvement. However, we believe the special adjustment for services that have no direct physician involvement, which we established as an interim policy until we can identify and propose better alternatives, continues to serve its purpose. We made a special adjustment to calculate payment for all services without direct physician involvement in response to the concerns of providers of technical services, particularly radiation oncologists and radiologists. Immediately eliminating the special adjustment would reduce payments for these services by roughly 12 percent for radiation oncologists, 9 percent for radiologists, and 4 percent for cardiologists. Overall, we estimate that practice expense payments for services that have no direct physician involvement would decrease by more than 18 percent. While the Lewin Group supported our general approach, they suggested possible, more limited refinements for allocating indirect expenses for these non-physician services. As noted above, we are currently analyzing the Lewin suggestions.

We look forward to working with GAO on these issues.

Attachments

Attachment 1

Summary of CMS Approach to Refining Practice Expense Relative Values for Medicare Physician Payment

We have summarized our activities in the August 2, 2001, Federal Register. A few examples of our major refinement efforts should illustrate the approach we have taken.

Socioeconomic Monitoring System (SMS) Data

The specialty-specific practice expense survey data is central to our ability to establish the appropriate resource-based relative payments for each service. Therefore, we have taken steps to improve the accuracy of this data. The first task given the contractor (the Lewin Group) charged with helping us analyze and improve our practice expense methodology was to generate suggestions for changes to the AMA's SMS survey instrument. As a result of our contractor's work and our own discussions, we have submitted a list of suggested refinements to the survey instrument that would make the survey data more useful for determining resource-based practice expense relative values. For example, we have suggested including questions on salaries for mid-level practitioners and on the costs of separately billable supplies, as well as on hours spent in uncompensated care. This data could allow us to calculate more accurate practice expense values, without having to use the assumptions and adjustments questioned in the report. We are hopeful that the practice level survey that the AMA expects to field in the near future will include most of our suggested revisions.

In order to increase the SMS sample size for each specialty and thus improve the reliability of this data, we have included the additional newer data as they become available. In this year's proposed physician fee schedule rule, we have proposed adding the 1999 SMS practice expense data to the data previously used to calculate the practice expense specialty-specific cost pools. We have also set out the criteria for our acceptance of supplementary practice expense survey data and have extended the deadline for the acceptance of this data for another two years. This gives specialties which are either under-represented or not included in the current SMS data the opportunity to provide us with more representative practice expense data.

Clinical Practice Expert Panels (CPEP) Data

Improving the accuracy of the CPEP data, which are used to allocate the direct practice expense to individual services, is also a target of our refinement efforts. In response to the publication of the 1998 proposed rule that described our new "top-down" approach, we received comments from physician specialty societies on the CPEP inputs for over 3000 different services. We are pleased that the AMA offered to set up a multi-specialty committee, the Practice Expense Advisory Committee (PEAC), to review the staff, supply and equipment inputs for each service and to send us recommendations on any refinement of these data. The PEAC is now up and running and has already sent us

recommendations on hundreds of services. The recommendations accepted so far include refining the inputs used to value the major evaluation and management services, which account for 24 percent of Medicare expenditures. The PEAC is also developing standardized inputs that could be applied to thousands of other services; therefore, we expect the pace of this refinement to accelerate quickly.

In addition to implementing most of the RUC-recommended refinements, we responded to comments on errors and anomalies in the CPEP data in both the November 1999 and November 2000 final rules. We also simplified the refinement of equipment inputs by combining both the procedure-specific and overhead equipment into a single equipment category. We deleted stand-by equipment and equipment used for multiple services at one time from the direct cost inputs because of the difficulty of allocating these costs at the code-specific level.

Calculation of Indirect Cost

Because changing the allocation method used to determine the procedure-specific indirect costs could have a large effect on the relative payment for all services, we requested that our contractor evaluate various options for calculating indirect costs. The final report, An Evaluation of the Health Care Financing Administration's Resource-Based Practice Expense Methodology, contains an analysis of the impacts of six alternative allocation methodologies. In confirming the suitability of our allocation methodology, the report concludes that "HCFA's approach is broadly consistent with most of the alternative methods. This consistency suggests that, from a broad perspective, no other allocation methodology offers a compelling reason to abandon the current HCFA approach."

Medicare Utilization Data

We have addressed concerns that potential errors in our specialty utilization data will have an effect on the calculation of practice expense RVUs. In the July 2000 proposed rule, we discussed our simulations that demonstrated that the small percentage of potential errors in our very large database have no adverse effect on specialty-specific practice expense RVUs. Therefore, the refinement of this data has been given a low priority.

Related GAO Products

Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments (GAO/HEHS-98-79, Feb. 27, 1998).

Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments (GAO/T-HEHS-98-105 March 3, 1998).

Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

Medicare Part B Drugs: Program Payments Should Reflect Market Prices (GAO-01-1142T, Sept. 21, 2001).

Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost (GAO-01-1118, Sept. 21, 2001).

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